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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MEDICAL DEVICES

Proposals on Development of Classification of Neurological Devices

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 882]

[Docket No. 78N-1000]

CLASSIFICATION OF NEUROLOGICAL DEVICES

Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency is proposing general rules applicable to the classification of all neurological devices. The Medical Device Amendments of 1976 requires the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: Class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual neurological devices, which are being published elsewhere in this issue of the FEDERAL REGISTER. The preamble also describes the activities of the Neurological Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of neurological devices.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

DEVICE CLASSIFICATION SYSTEM

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three catogories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and is substantially equivalent to a device classified under this scheme, is also classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

RELATED REGULATIONS

In the FEDERAL REGISTER of July 28, 1978 (43 FR 32988), the Commissioner issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the FEDERAL REGISTER of May 19, 1975 (40 FR 21848).

ACTIVITIES OF PANEL

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Neurological Device Classification Panel (the Panel) was originally chartered on October 15, 1974, as the Panel on Review of Neurological Devices. On January 26, 1976, FDA placed a report of the Panel's tentative classification recommendations on file with the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the FEDERAL REGISTER of June 25, 1976 (41 FR 26245).

On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the Panels deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of neurological devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and previous Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the FEDERAL REGISTER of November 29, 1977 (42 FR 60792). At meetings held on January 13, 1978 and April 21, 1978, the Panel changed its previous recommendations concerning the clasification of several devices. An addendum to the Panel report showing these changes has been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual neurological device proposed classification regulations. Interested persons may review these documents in the office at the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday.

LIST OF NEUROLOGICAL DEVICES

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of neurological devices. The Panel supplemented the list utilizing its members' knowledge of

neurological devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

The Commissioner is proposing to establish a new Part 882 in Title 21 of the Code of Federal Regulations. Part 882 will consist of sections identifying each neurological device with a brief narrative description and stating the classification of that device. A list of the neurological devices appears elsewhere in this preamble.

Individual Neurological Device Classification Regulation

Elsewhere in this issue of the Federal Register, the Commissioner is issuing 103 individual proposed regulations to classify each neurological device. The Commissioner is proposing to classify 26 neurological devices into class I (general controls), 66 neurological devices into class II (performance standards), and 11 neurological devices into class III (premarket approval). The Commissioner also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning a neurological device includes the information described below.

1. *Identification.* The Panel recommendation and proposed FDA classification regulation each include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 882.1, manufacturers who submit premarket notification submissions under section 510(k) of the act and Part 807 of the regulations cannot show merely that a newly offered device is accurately described by the section title and identification provisions of a classification regulation. although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act of it is not substantially equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The commissioner believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR § 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panel did not recommend that any device be exempted at this time from section 510 or section 519 of the act, the panel did recommend that the manufacturers of several class I devices be exempted from good manufacturing practice regulations (and thus from the records and reports requirements in these regulations) in the manufacture of these devices. The Commissioner's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high" or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high" or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the Commissioner is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from an advisory committee's recommendation, the Commissioner is adopting the committee's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and familiarity with, the devices under review. Reliance upon clinical experience and judgement was particularly common when the Panel considered a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(a)(2) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in this section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94-853, 94th Congress, 2d Session 40 (1976)). The Commissioner has determined that clinical experience and judgment are valid scientific evidence for classifying certain devices.

In many cases, FDA sought data and information concerning the classification of a device in addition to that cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual neurological device regulations. The Commissioner is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by neurological devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the use of a device.

In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by neurological devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) and future regulations requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify risks to health to be addressed by FDA requirements in addition to those identified in the classification recommendations and regulations.

Proposed Classification

Each proposed regulation to classify a neurological device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 882 in which the device classification will be codified.

The Commissioner cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends to be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high" or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other neurological devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

The Commissioner is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. At a later date, however, the Commissioner will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the Federal Register.

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

The Panel recommended that several neurological devices that are recommended for classification into class I be exempted from the good manufacturing practice (GMP) regulation. The GMP regulation was published in final form in the Federal Register of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendation, the GMP regulation had not been promulgated, and the agency had not yet developed criteria for exempting a class I device from the GMP regulation.

The Commissioner has decided that the agency will consider exempting a class I device from the GMP regulations if any one of the following requirements is met:

1. Based on adequate information about current practices in the manufacture of the device and about user experience with the device, the agency has determined that application of the GMP regulation will not improve the safety and effectiveness of the device.
2. The agency has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or through testing that is done routinely before use, e.g., testing a clinical laboratory reagent with positive and negative controls.
3. The agency has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

List of Neurological Devices

The following is a list of neurological devices that shows the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Neurological Diagnostic Devices		
882.1020	Rigidity analyzer	78N-1001	II
882.1030	Ataxiagraph	78N-1002	I
882.1200	Two-point discriminator	78N-1003	I
882.1240	Echoencephalograph	78N-1004	II
882.1275	Electroconductive media	78N-1005	II
882.1310	Cortical electrode	78N-1006	II
882.1320	Cutaneous electrode	78N-1007	II
882.1330	Depth electrode	78N-1008	II
882.1340	Nasopharyngeal electrode	78N-1009	II
882.1350	Needle electrode	78N-1010	II
882.1400	Electroencephalograph	78N-1011	II
882.1410	Electroencephalograph electrode/lead tester	78N-1012	II
882.1420	Electroencephalogram (EEG) signal spectrum analyzer	78N-1013	I
882.1430	Electroencephalograph test signal generator	78N-1014	I
882.1460	Nystagmograph	78N-1015	II
882.1480	Neurological endoscope	78N-1016	II
882.1500	Esthesiometer	78N-1017	I

Section	Device	Docket No.	Class
	SUBPART B—NEUROLOGICAL DIAGNOSTIC DEVICES—Continued		
882.1525	Tuning fork	78N-1018	I
882.1540	Galvanic skin response measurement device	78N-1019	I
882.1550	Nerve conduction velocity measurement device	78N-1020	II
882.1560	Skin potential measurement device	78N-1021	II
882.1570	Powered direct-contact temperature measurment device	78N-1022	II
882.1610	Alpha monitor	78N-1023	II
882.1620	Intracranial pressure monitoring device	78N-1024	II
882.1700	Percussor	78N-1025	I
882.1750	Pinwheel	78N-1026	I
882.1790	Ocular plethysmograph	78N-1027	III
882.1825	Rheoencephalograph	78N-1028	III
882.1835	Physiological signal amplifier	78N-1029	II
882.1845	Physiological signal conditioner	78N-1030	II
882.1855	Physiological signal telemetry system	78N-1031	II
882.1870	Evoked response electrical stimulator	78N-1032	II
882.1880	Evoked response mechanical stimulator	78N-1033	II
882.1890	Evoked response photic stimulator	78N-1034	II
882.1900	Evoked response auditory stimulator	78N-1035	II
882.1925	Ultrasonic scanner calibration test block	78N-1036	I
882.1950	Tremor transducer	78N-1037	II
	SUBPARTS C—D [RESERVED]		
	SUBPART E—NEUROLOGICAL SURGICAL DEVICES		
882.4030	Skull plate anvil	78N-1038	I
882.4060	Ventricular cannula	78N-1039	I
882.4100	Ventricular catheter	78N-1040	II
882.4125	Neurosurgical chair	78N-1041	I
882.4150	Scalp clip	78N-1042	II
882.4175	Aneurysm clip applier	78N-1043	II
882.4190	Clip forming/cutting instrument	78N-1044	I
882.4200	Clip removal instrument	78N-1045	I
882.4215	Clip rack	78N-1046	I
882.4250	Cryogenic surgical device	78N-1047	II
882.4275	Dowel cutting instrument	78N-1048	I
882.4300	Manual drill, burr, trephine, and accessories	78N-1049	II
882.4305	Powered compound drill, burr, trephine, and accessories	78N-1050	II
882.4310	Powered simple drill, burr, traphine, and accessories	78N-1051	II
882.4325	Drill handpiece (brace)	78N-1052	II
882.4360	Electric drill motor	78N-1053	II
882.4370	Pneumatic drill motor	78N-1054	II
882.4400	Radiofrequency lesion generator	78N-1055	II
882.4440	Neurosurgical headrest	78N-1057	I
882.4460	Neurosurgical head holder (skull clamp)	78N-1058	II
882.4500	Cranioplastry material forming instrument	78N-1059	I
882.4525	Microsurgical instrument	78N-1061	I
882.4535	Nonpowered neurosurgical instrument	78N-1062	I
882.4545	Shunt system implantation instrument	78N-1063	I
882.4560	Stereotaxic instrument	78N-1064	II
882.4600	Leukotome	78N-1065	I
882.4650	Nrurosurgical suture needle	78N-1066	I
882.4700	Cottonoid paddle	78N-1067	II
882.4725	Radiofrequency lesion probe	78N-1068	II
882.4750	Skull punch	78N-1069	I
882.4800	Self-retaining retractor	78N-1070	II
882.4840	Manual rongeur	78N-1071	II
882.4845	Powered rongeur	78N-1072	II
882.4900	Skullplate screwdriver	78N-1073	I
882.4925	Sponge for internal use	78N-1074	II
	SUBPART F—NEUROLOGICAL THERAPEUTIC DEVICES		
882.5030	Methyl methacrylate for aneurysmorrhaphy	78N-1075	II
882.5050	Biofeedback device	78N-1076	II
882.5070	Bite block	78N-1077	II
882.5150	Intravascular occluding catheter	78N-1078	III
882.5175	Carotid artery clamp	78N-1079	II
882.5200	Aneurysm clip	78N-1080	II
882.5225	Implanted malleable clip	78N-1081	II
882.5335	Aversive conditioning device	78N-1082	II
882.5250	Burr hole cover	78N-1083	II
882.5275	Nerve cuff	78N-1084	III
882.5300	Methyl methacrylate for cranioplasty	78N-1085	II
882.5320	Preformed alterable cranioplasty plate	78N-1086	II
882.5330	Preformed nonalterable cranioplasty plate	78N-1087	II
882.5360	Cranioplasty plate fastener	78N-1088	II
882.5500	Lesion temperature monitor	78N-1089	II
882.5550	Central nervous system fluid shunt and components	78N-1090	II
882.5800	Cranial electrotherapy stimulator	78N-1091	III
882.5810	External functional neuromuscular stimulator	78N-1092	II
882.5820	Implanted cerebellar stimulator	78N-1093	III
882.5830	Implanted diaphragmatic/phrenic nerve stimulator	78N-1094	III
882.5840	Implanted intracerebral/subcortical stimulator for pain relief	78N-1095	III
882.5850	Implanted spinal cord stimulator for bladder evacuation	78N-1096	III
882.5860	Implanted neuromuscular stimulator	78N-1097	III
882.5870	Implanted peripheral nerve stimulator for pain relief	78N-1098	II
882.5880	Implanted spinal cord stimulator for pain relief	78N-1099	II
882.5890	Transcutaneous electrical nerve stimulator for pain relief	78N-1100	II
882.5900	Preformed craniosymostosis strip	78N-1101	II
882.5910	Dura substitute	78N-1102	II

Section	Device	Docket No.	Class
SUBPART F—NEUROLOGICAL THERAPEUTIC DEVICES—Continued			
882.5940	Electroconvulsive therapy device	78N-1103	II
882.5950	Artificial embolization device	78N-1104	III
882.5960	Skull tong for traction	78N-1105	II

DEVICES CONSIDERED BY TWO OR MORE PANELS

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Neurological Device Classification Panel and by other panels:

1. The Physical Medicine Device Classification Panel recommended that the two-point discriminator esthesiometer and the touch discriminator esthesiometer be classified into class I. The Neurological Device Classification Panel recommended that the two-point discriminator be classified into class I. The Commisssioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the two-point discriminator into class I, and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

2. The Physical Medicine Device Classification Panel recommended that the battery-powered skin resistance meter be classified into class I and that the AC-powered skin resistance meter be classified into class II. The Neurological Device Classification Panel recommended that the neurodermamometer for galvanic skin response measurement, whether battery-powered or AC-powered, be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the galvanic skin response measurement device into class II, and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

3. The Physical Medicine Device Classification Panel recommended that the external functional neuromuscular stimulator be classified into class II. The Neurological Device Classification Panel recommended that the external neuromuscular stimulator be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the external functional neuromuscular stimulator into class II, and is publishing the two panel's recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

4. The Anesthesiology Device Classification Panel recommended that the electrophrenic pacer be classified into class III. The Neurological Device Classification Panel recommended that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III. The Commissioner has determined that these devices are the same. Therefore, the Commissioner is proposing a single regulation classifying the implanted diaphragmatic/phrenic nerve stimulator into class III and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

5. The Orthopedic Device Classification Panel recommended that the implanted peroneal stimulator be classified into class II. The Neurological Device Classification Panel recommended that the implanted neuromuscular stimulator be classified into class III. The Commissioner has determined that these devices are the same. Therefore, the Commissioner is proposing a single regulation classifying the implanted neuromuscular stimulator into class III and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

6. The Neurological Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Chronaximeter	Physical medicine.
Dynamometer	Physical medicine; orthopedic; anesthesiology.
Electromyograph	Physical medicine.
Computed tomography X-ray scanner.	Radiology.
Angiographic catheter	Radiology; cardiovascular.
Angiographic wire guide and accessories.	Do.
Angiographic needle	Do.
Fiberoptic surgical field illuminator.	General and plastic surgery.
Surgical microscope system.	General and plastic surgery; ophthalmic; ear, nose, and throat.
Electrosurgical apparatus.	Cardiovascular; general and plastic surgery; anesthesiology; gastroenterology and urology; dental.
Legature-passing and knot-tying instrument.	General and plastic surgery.
Neurosurgical headlight	General and plastic surgery; ear, nose, and throat; dental.
Ultrasonic bone-cutting instrument.	Orthopedic.
Pneumoencephalographic chair.	Radiology.
Manual saw and accessories.	Cardiovascular; orthopedic; ear, nose, and throat; general and plastic surgery.
Powered saw and accessories.	Cardiovascular; orthopedic; dental; ear, nose, and throat.
Sponge (external use)	General and plastic surgery; dental; ophthalmic.
Manual retractor	Dental; ear, nose, and throat; gastroenterology and urology; ophthalmic; orthopedic; general and plastic surgery; obstetrics and gynecology.
Hemostatic clip applier	General and plastic surgery.
Electroanesthesia stimulator.	Anesthesiology.

The Commissioner is not at this time publishing the Neurological Device Classification Panel's recommendations to classify the devices listed above. The Commissioner will publish these recommendations, and proposed classification regulations, when FDA publishes the recommendations of other panels that reviewed the devices.

TISSUE ADHESIVES

At a future date, FDA will publish in the FEDERAL REGISTER a final regulation stating that one neurological device (tissue adhesives for aneurysmorrhaphy) is classified into class III (premarket approval) because of transitional provisions of the act in section 520(1) (21 U.S.C. 360j(1)). The transitional provisions classify into class III any device previously regarded by FDA as a new drug. At the time FDA publishes this regulation, the agency also will publish the Panel's recommendations regarding tissue adhesives for aneurysmorrhaphy and for general neurosurgical use.

ENVIRONMENTAL IMPACT

The Commissioner has carefully considered the environmental effects of proposed § 882.1 and of the proposed neurological device classification regulations and because the proposed actions will not significantly affect the quality of the human environment has concluded that an environmental impact statement is not required. A

copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)), and under authority delegated to the Commissioner (21 U.S.C. 5.1), the Commissioner proposes that Chapter I of Title 21 of the code of Federal Regulations be amended by adding new Part 882, Subpart A, to read as follows:

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Sec.
882.1 Scope.

AUTHORITY: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., use both as a diagnostic device and as a therapeutic device) is listed in the subpart representing one use of the device, rather than in two or more subparts.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding proposed § 882.1. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32858 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1001]

MEDICAL DEVICES

Classification of Rigidity Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rigidity analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medcial Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administraion, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of rigidity analyzers:

1. Identification: A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's limb to determine the effectiveness of drugs or other treatment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the rigidity analyzer be classified into class II (performance standards) to require that the performance characteristics be maintained at a satisfactory level. The Panel believes that general controls will not provide sufficient control over these characteristics. The function of this device is to quantify a physiological measurement; therefore, the Panel believes that the device should provide accurate and repeatable measurements. The Panel also recommends that FDA require the labeling of this device to indicate the limitations of the device. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Rigidity analyzers have been in use for many years. The Panel members based their recommendation on their experience with these rigidity analyzers.

5. Risks to health: Incorrect treatment. If the device measurements are not sufficiently accurate, the assessment of the patient's response to therapy may be in error, and the physician may prescribe incorrect treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the rigidity analyzer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act 9 (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to add a new Part 882 as follows:

PART 882—NEUROLOGICAL DEVICES

Subpart A—[Reserved]

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.

(a) *Identification.* A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's

limb to determine the effectiveness of drugs or other treatments. •

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32859 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1002]

MEDICAL DEVICES

Classification of Ataxiagraphs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ataxiagraphs into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by Janurary 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ataxiagraphs:

1. Identification: An ataxigraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class I (general controls) because it make no electrical contact with the patient and presents no inherent hazards. It is used to help quantify clinical observations only and does not replace subjective evaluation. Because no particular precision is required, the Panel believes that a performance standard is not necessary and that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience in evaluating ataxia and familiarity with these devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ataxiagraph be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1030 as follows:

§ 882.1030 Ataxiagraph.

(a) *Identification.* An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32860 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1003]

MEDICAL DEVICES

Classification of Two-Point Discriminators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying two-point discriminators into class I (general controls). The FDA is also publishing the recommendations of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel that the device by classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of two-point discriminators:

1. Identification: A two-point discriminator is a device with points used for testing a patient's touch discrimination.

2. Recommended Classification: Class I (general controls). The Neurological Device Classification Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The Physical Medicine Device Classification Panel recommended no exemptions.

3. Summary of reasons for recommendation: The two-point discriminator is an extremely simple mechanical device which is routinely used in neurological examinations. It presents no hazards to health and requires no special materials or properties. The panel members noted that an ordinary object such as a paper clip will often serve the same purpose as this device. Because the Neurological Device Classification Panel believes that the functional capabilities and qualities of the device are easily determined by examination of the device itself, the Panel believes that control of manufacturing methods for manufacturing the device is unnecessary.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their familiarity with this device and its routine use in neurological examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that two-point discriminators be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that two-point discriminators be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CRF Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1200 as follows:

§ 882.1200 Two-point discriminator.

(a) *Identification.* A two-point discriminator is a device with points used for testing a patient's touch discrimination.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1978; submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32861 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1004]

MEDICAL DEVICES

Classification of Echoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echoencephalographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of echoencephalographs:

1. Identification: An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, or doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that echoencephalographs be classified into class II (performance standards) to control the hazards of excessive ultrasonic power output, electric shock, and explosive environments and to assure usable resolution (image quality) and accuracy. The Panel believes that records and images obtained from this device are valuable aids in the diagnosis of various cranial disorders. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their knowledge and experience with ultrasonic diagnostic instruments. Dr. Mark Dyken, a Panel member, stated that laboratory experiments to determine the adverse effects on the eyes produced by the highest level of clinically used ultrasound had been conducted. The results (Ref. 1) indicated no adverse effects.

5. Risks to health: a. Excessive ultrasonic output: An excess level of power could cause tissue damage by cavitation (bubble formation and activity), thermal effects, or nonthermal mechanisms.

b. Electric shock. Failure of the transducer insulation could allow high voltage to reach the patient.

c. Explosion. If the device is not explosion proof it might cause an explosion if used in an environment having flammable gases.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the echoencephalograph be classifed into class II (performance standards). Stratmeyer's review (Ref. 2) of the possible biological effects of ultrasound includes references to two investigations showing that exposures of ultrasonic energy similar to those used in echoencephalography may cause alterations in the central nervous system of dogs (Ref. 3) and nonhuman primates (Ref. 4). Although those investigations are cause for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has also reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 2).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

FDA will soon publish a notice of intent in the FEDERAL REGISTER announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency will consider taking is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 2636 et seq.).

The Commissioner believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for the echoencephalograph because general controls by themselves are insufficient to control the risks to health. The Commissioner also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fisheries Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday:

1. Maroon, J., R. L. Campbell, and M. Dyken, *Stroke*, 1:122-127, 1970.

2. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—a Public Health View," Proceedings of a Symposium on Biological Effects and Characterization of Ultrasound Sources, HEW publication (FDA) 78-8044, 1978.

3.Tsutsumi, Y., K. Sano, T. Kuwabara, T. Takakura, K. Hayakawa, T. Suzuki, and M. Katanuma, "A New Portable Echo-encephalograph, Using Ultrasonic Transducers and its Clinical Application," *Medical Electronics and Biological Engineering*, 2:21-29, 1964.

4. Hu, J. H. and W. D. Ulrich, "Effects of Low-Intensity Ultrasound on the Central Nervous System of Primates" *Aviat. Space Environ, Med.*, pp. 640-643, June, 1976.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (First Meeting), Jan. 22-23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1240 as follows:

§ 882.1240 Echoencephalograph.

(a) *Identification.* An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32862 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1005]

MEDICAL DEVICES

Classification of Electroconductive media

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroconductive media into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroconductive media:

1. Identification: Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance

(resistance to alternating current) of the contact between the electrode surface and the skin.

2. Recommended classification; Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electroconductive media be classified into class II (performance standards) becuase the material is applied to the patient's skin and carries electrical current and the Panel believes that performance standards are necessary to control the material's electrical conductivity and compatibility with the skin. The need for specifying an adequate acid/base buffer to avoid skin burns was also noted by the Panel. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Various substances have been used as electroconductive media for many years in conjunction with cutaneous electrodes. The Panel members based their recommendation on their experience ith these electroconductive media.

5. Risks to health: a. Chemical skin burn casued by pH change: The electrical current can produce adverse chemical changes in the conductive media unless the media contain a buffer.

b. Toxic reactions: A toxic substance in the media could attack the skin or be absorbed through the skin.

c. Unacceptable recording quality: Material which does not maintain sufficiently low resistance to the electrical current may impair the quality of the recorded signal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroconductive media be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding New § 882.1275 to read as follows:

§ 882.1275 Electroconductive media.

(a) *Identification.* Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32863 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1006]

MEDICAL DEVICES

Classification of Cortical Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cortical electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. these actions are being taken under the medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cortical electrodes:

1. Identification: A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cortical electrode be classified into class II (performance standards because the device uses materials that come into contact with the body and should be controlled, and the device has performance characteristics which should be maintained at an acceptable level. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel also recommends that the method of sterilization be stated in the device labeling. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Cortical electrodes have been in use for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. Sterility: If not sterilized, the device may introduce contaminants into the brain.

b. Local irritation: The electrode materials may cause toxic or adverse reactions when placed in contact with brain tissue.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cortical electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1310 to read as follows:

§ 882.1310 Cortical electrode.

(a) *Identification:* A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32864 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1007]

MEDICAL DEVICES

Classification of Cutaneous Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cutaneous electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cutaneous electrodes:

1. Identification: A cutaneous electrode is an electrode which is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cutaneous electrode be classified into class II because the electrical properties of the device must be controlled to assure that when physiological signals are recorded, they are adequately reproduced; to prevent burns when the device is used to apply stimulation; and to assure that only materials with known and acceptable properties are used in electrodes. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Cutaneous electrodes have been in use for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. Burns. Poor design or incorrect application of the electrodes could result in skin burns when the electrodes are used for stimulation.

b. Toxic reactions. Material or substances in the electrodes that are in contact with the skin could produce adverse reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cutaneous electrodes be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1320 to read as follows:

§ 882.1320 Cutaneous electrode.

(a) *Identification.* A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32865 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1008]

MEDICAL DEVICES

Classification of Depth Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying depth electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the

future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of depth electrodes:

1. Identification: A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that depth electrodes be classified into class II (performance standards) because they use materials that come into contact with the brain and because the geometric configuration and performance characteristics of this device must be controlled to assure that the device is safe and effective. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these electrodes.

5. Risks to health: a. Local irritation: Improper materials in the electrode can adversely react with the tissue.

b. Damage to brain tissue: The electrode geometry must be such that it spreads rather than cuts tissue during insertion.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the depth electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1330 as follows:

§ 882.1330 Depth electrode.

(a) *Identification.* A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32866 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1009]

MEDICAL DEVICES

Classification of Nasopharyngeal Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasopharyngeal electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nasopharyngeal electrodes:

1. Identification: A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nasopharyngeal electrode be classified into class II (performance standards) to assure that when physiological signals are recorded, they are adequately reproduced and to control the materials used in the electrode to prevent injury to the sensitive internal surface of the nose or the pharynx. The Panel believes that general controls alone will not be sufficient to control these properties. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with devices of this type.

5. Risks to health: a. Improper positioning: If the device is poorly designed or is not accompanied by adequate directions for use, an accurate reproduction of the physiological signal may not be obtained.

b. Tissue damage: If the device is poorly designed or is made from inflexible material, the device could injure the inside of the nose or the pharynx.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nasopharyngeal electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1340 as follows:

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification.* A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32867 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1010]

MEDICAL DEVICES

Classification of Needle Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying needle electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of needle electrodes:

1. Identification: A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the needle electrode, because it penetrates the skin, be classified into class II (performance standards) to assure that the device is sterile. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard should require that the device be capable of being sterilized. The Panel recommends that FDA require that the manufacturer furnish users with adequate instructions for achieving sterile use and that the labeling indicate the maximum safe stimulating current that can be applied to a specific electrode. The Panel believes further tht the conducting and insulating materials of the electrode should meet standards to reduce the risk of toxic effects. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Needle electrodes have been used for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. High current-density burns: Burns may result if the exposed conducting surface area is too small for the stimulation current being used.

b. Site-of-entry infection: Infection may result with an unsterile needle or improper technique.

c. Systemic infection: An unsterile needle may result in circulatory system infection.

d. Toxicity: Materials used for the needle or for insulation my be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the needle electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1350 as follows:

§ 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32868 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1011]

MEDICAL DEVICES

Classification of Electroencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalographs:

1. Identification: An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the electroencephalograph be classified into class II (performance standards) to ensure that the electroencephalogram is adequately reproduced and that neurological conditions are accurately diagnosed. The Panel believes that electrical safety standards are needed to prevent electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and familiarity with electroencephalography. Electroencephalographs have been in clinical use for many years and are standard diagnostic instruments well known to neurologists.

5. Risks to health: a. Misuse: Use of this device requires special training. Use by unqualified persons could result in improper diagnosis and treatment.

b. Misdiagnosis: Distortion of the physiological signal could cause a misdiagnosis and lead to improper treatment of a neurological condition.

c. Electrical shock: Leakage current can be especially hazardous because the device makes a low resistance contact with the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalographs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1400 as follows:

§ 882.1400 **Electroencephalograph.**

(a) *Identification.* An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32869 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1012]

MEDICAL DEVICES

Classification of Electroencephalograph Electrode/Lead Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalograph electrode/lead testers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become ef-

fective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalograph electrode/lead testers:

1. Identification: An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the electroencephalograph electrode/lead tester be classified into class II because the Panel believes that performance standards are needed to assure that the device performs the required measurement accurately and to protect the patient from electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members are familiar with the techniques of electroencephalography. The Panel members based their recommendation on their knowledge that predictable electrical contact is necessary to obtain a satisfactory recording.

5. Risks to health: Electric shock: The patient might receive an electrical shock from the device if it is poorly designed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalograph electrode/lead tester be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks ot health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1410 as follows:

§ 882.1410 Electroencephalograph electrode/lead tester

(a) *Identification.* An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32870 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1013]

MEDICAL DEVICES

Classification of Electroencephalogram (EEG) Signal Spectrum Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalogram (EEG) signal spectrum analyzers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979.

The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsehere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalogram (EEG) signal spectrum analyzers:

1. Identification: An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified in class I (general controls) because the device does not make contact with the patient and no hazards have been identified. This device is used to process data obtained from an electroencephalograph (EEG) device and to display the results. The Panel believes that the information obtained from this device is not used in a manner which involves any risks to health. The Panel believes that general controls will suffice to control this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience in the interpretation of EEG information and their familiarity with the technique of spectral analysis.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalogram (EEG) signal spectrum analyzer be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1420 as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification.* An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: Nov. 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32871 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1014]

MEDICAL DEVICES

Classification of Electroencephalograph Test Signal Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalograph test signal generators into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalograph test signal generators:

1. Identification: An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: This device makes no electrical contact with the patient and presents no inherent hazards. The Panel believes that the safety and effectiveness of the device can be controlled by general controls.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on extensive personal experience with electroencephalography and familiarity with these test devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalograph test signal generator be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1430 as follows:

§ 882.1430 Electroencephalograph test signal generator.

(a) *Identification.* An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32872 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1015]

MEDICAL DEVICES

Classification of Nystagmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nystagmographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classsifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are

being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. the Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nystagmographs:

1. Identification: A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: the Panel recommends that the nystagmograph be classified into class II (performance standards) because the device may be powered by an external electrical source. Some devices of this type make low resistance electrical contact with the skin therefore, malfunction is particularly dangerous if the device is not properly designed. The Panel believes that performance standards are necessary to assure that the device measurements are accurate. The Panel also recommends that FDA require labeling which identifies the limitations of the measurement. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device, which is used extensively.

5. Risks to health: Electrical shock: Excessive leakage current could cause injury, or a malfunction could result in dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nystagmograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1460 as follows:

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32873 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1016]

MEDICAL DEVICES

Classification of Neurological Endoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurological endoscopes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of neurological endoscopes:

1. Identification: A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the neurological endoscope be classified into class II (performance standards) because the light intensity should be controlled to avoid burns, the optical distortion should be limited so that the field of view is faithfully reproduced, and the device should be subject to an electrical safety standard because it makes contact with body fluid. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members

based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Infection: The device could introduce bacteria into cerebrospinal fluid if the device is not adequately sterilized. (b) Burns: Excessive illuminating power can cause burns. (c) Electrical shock: The patient may receive an electrical shock because a low resistance path exists between the patient and the instrument.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the neurological endoscope be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1480 as follows:

§ 882.1480 Neurological endoscope.

(a) *Identification.* A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32874 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1017]

MEDICAL DEVICES

Classification of Esthesiometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esthesiometers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of esthesiometers:

1. Identification: An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempted from good manufacturing practices regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that the esthesiometer be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This simple device presents no risks to health, and the examiner can easily determine whether the device is effective by examining it. The Panel believes that manufacturers of the device should not be required to comply with good manufacturing practice regulations in manufacturing the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device because it is routinely used by neurologists as an aid to physical examination.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the esthesiometer be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that the esthesiometer be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing practice regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1500 as follows:

§ 882.1500 Esthesiometer.

(a) *Identification.* An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulation in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments,

and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32875 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1018]

MEDICAL DEVICES

Classification of Tuning Forks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tuning forks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tuning forks:

1. Identification: A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The tuning fork is a well-known device which contains no hazards to health and which can be adequately regulated by general controls. The Panel recommends that manufacturers of the device not be required to comply with good manufacturing practice regulations in manufacturing the device because tuning forks require no special qualities for medical use.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and its long history of routine use in neurological examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the tuning fork be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner is also proposing that the tuning fork be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing regulations, because all defects related to safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1525 as follows:

§ 882.1525 Tuning fork.

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32876 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1019]

MEDICAL DEVICES

Classification of Galvanic Skin Response Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying galvanic skin response measurement devices into class II (performance standards). The FDA is also publishing the recommendations of the Neurological Device Classification Panel that these devices be classified into class II and of the Physical Medicine Device Classification Panel that these devices be classified into class II if they are AC powered and into class I if they are battery powered. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and

Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8758 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of galvanic skin response measurement devices:

1. Identification: A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

2. Recommended classification: The Neurological Device Classification Panel recommends that these devices be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Physical Medicine Device Classification Panel recommends that this device be classified into class II if it is powered by alternating current (AC) and that establishing a performance standard for this device be a low priority. The Physical Medicine Device Classification Panel recommends that if the devices are battery powered, they be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Neurological Device Classification Panel recommends that galvanic skin response measurement devices be classified into class II because the Panel believes that the characteristics of the electrical current, which is applied to measure the resistance of the skin, should be controlled to prevent injury. The Panel also believes that the measurement limitations inherent in the use of the device should be clearly specified by manufacturers in the device's labeling. The Physical Medicine Device Classification Panel recommends that AC-powered galvanic skin response measurement devices be classified into class II because they believe that a standard is needed to prevent electrical shock and burns from leakage of electrical current. The Physical Medicine Device Classification Panel recommends that battery-powered galvanic skin response measurement devices be classified into class I because they believe that the risks of electrical shock and burns are not as great with battery-powered devices as with AC-powered devices and the safety and effectiveness of the battery-powered device can be reasonably assured by general controls. Both the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel believe that a standard will provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: a. Electrical shock: Excessive current could cause injury, or a malfunction could result in an electric shock.

b. Inaccurate measurements: An inaccurate diagnosis could result if the device does not measure skin resistance accurately.

PROPOSED CLASSIFICATION

The Commissioner does not agree with the Physical Medicine Device Classification Panel recommendation that the battery-powered galvanic skin response measurement device be classified into class I (general controls). Although it is true that there is less risk of electrical shock from a battery-powered device than from an AC-powered device, there still is enough of a risk of electrical shock from the battery-powered device to justify the application to it of a performance standard. The Commissioner therefore agrees with the Neurological Device Classification Panel and is proposing that the galvanic skin response measuring device, whether battery-powered or AC-powered, be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1540 as follows:

§ 882.1540 Galvanic skin response measurement device.

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin (including the electrode/skin interface impedance).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32877 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1020]

MEDICAL DEVICES

Classification of Nerve Conduction Velocity Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nerve conduction velocity measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drug proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nerve conduction velocity measurement devices:

1. Identification: A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that nerve conduction velocity measurement devices be classified into class II (performance standards) because the electrical properties of the device must be controlled to assure that nerve conduction velocity will be accurately measured and to prevent burns and electrical shock from the electrical stimulus that the device applies to the patient. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with these devices.

5. Risks to health: a. Burns: The device includes an electrical stimulator which may burn the skin if the electrical current is excessive.

b. Electrical shock: Leakage current can be especially dangerous because the device makes a low resistance contact with the patient.

c. Misdiagnosis: Inaccurate measurement of the nerve conduction velocity can result in improper treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nerve conduction velocity measurement devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1550 as follows:

§ 882.1550 Nerve conduction velocity measurement device.

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measureing and displaying the nerve conduction time.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32878 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1021]

MEDICAL DEVICES

Classification of Skin Potential Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation clasifying skin potential measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, RM. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological device Classification Panel, an FDA advisory committee, made the following recommendation will respect to the classfication of skin potential measurement devices:

1. Identification: A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the skin potential measurement device be classified into class II (performance standards) to ensure that the device provides accurate measurements and to prevent electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these devices.

5. Risks to health: a. Misdiagnosis: If a device that is not calibrated and accurate is used for diagnosis of disease conditions, inappropriate treatments may be prescribed.

b. Electrical shock: Excessive leakage current can cause electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the skin potential measurement device be classified into class II (performance standards). The Com-

missioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1560 as follows:

§ 882.1560 Skin potential measurement device.

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, RM. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: Nov. 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32879 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1022]

MEDICAL DEVICES

Classification of Powered Direct-Contact Termperature Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered direct-contact temperature measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered direct-contact temperature measurement devices:

1. Identification: A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered direct-contact temperature measurement device be classified into class II (performance standards) to insure adequate sensitivity to temperature differences and to prevent accidental reversal of temperature-sensing elements. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device and the techniques of temperature measurement.

5. Risks to health: Misdiagnosis: Accidentally reversed sensing elements or lack of adequate sensitivity to temperature differences can result in misdiagnosis and improper treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the powered direct-contact temperature measurement device be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1570 as follows:

§ 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification.* A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32880 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1023]

MEDICAL DEVICES

Classification of Alpha Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha monitors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of alpha monitors:

1. Identifidcation: An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device, which is a specialized version of the electroencephalograph, be classified into class II (performance standards) to assure control of electrical safety and that the device performs properly. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the clinical use of electroencephalography and related devices.

5. Risks to health: a. Misdiagnosis: If the phyhsiological signal is distorted or the electrical filtering process does not correctly select the alpha wave, the physician may make an erroneous assessment of the patient's neurological state.

b. Electrical shock: Excessive leakage current could cause injury, or a malfunction could result in dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the alpha monitor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1610 as follows:

§ 882.1610 Alpha monitor.

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32881 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1024]

MEDICAL DEVICES

Classification of Intracranial Pressure Monitoring Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intracranial pressure monitoring devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation

with respect to the classification of intracranial pressure monitoring devices:

1. Identification: An intracranial pressure monitoring device is a device used for short term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor and interconnecting hardware.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intracranial pressure monitoring devices be classified into class II because the Panel believes that the device needs to be subject to a performance standard to assure that the pressure measurements obtained from the device are accurate, to prevent brain damage due to an excessively bulky device, and to assure that the device is designed to prevent leakage of cerebrospinal fluid. The Panel also recommends that intracranial pressure monitoring systems be required to incorporate an alarm that is triggered by sudden or abnormal increases in intracranial pressure. The Panel recommends that intracranial pressure monitoring devices be classified into class II (performance standards) but that the recommendation apply only to short-term clinical applications of intracranial pressure monitoring because sufficient clinical data are not available to evaluate long-term use and because the Panel is not aware of a commercially available product intended for long-term use. Although a variety of devices has been used to monitor intracranial pressure, they all consist essentially of a manometer (pressure indicator) inserted through a hole in the skull so that a pressure connection is made with the fluid that surrounds the brain. This procedure presents risks of brain damage and infection. However, the Panel believes that, in certain circumstances, the information obtained by monitoring intracranial pressure is sufficiently valuable to justify the risks. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Intracranial pressure monitoring devices have been used in various forms for several years. The Panel members based their recommendation on their clinical experience with intracranial pressure monitoring devices.

5. Risks to health: a. Brain damage by pressure. An excessively bulky device could exert damaging pressure on the brain.

b. Brain damage by surgical trauma. The surgery involved in inserting this device presents inherent risks.

c. Inaccurate pressure readings. A defect in the device can result in inaccurate pressure readings.

d. Leakage of cerebrospinal fluid. The device needs to have a tight seal to prevent leakage of cerebrospinal fluid.

e. Infection. Infection may result if the device is not sterile or if contaminants enter the surgical opening.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation to classify intracranial pressure monitoring devices into class II (performance standards). The Commissioner also agrees with the Panel's decision to distinguish between the usual short-term application of the intracranial pressure monitoring device and the possible long-term application of the device. Sufficient clinical data are not available to permit evaluation of long-term use of the device.

The FDA has reviewed literature relating to intracranial pressure monitoring devices and has found that several devices have been used which measure pressure by a direct connection with the fluid in the subdural space of the brain. (Refs. 1 through 4). Epidural devices (inserted between the cranium and the dura mater; i.e., the tough, outer membrane covering the brain) are also currently being used to monitor intracranial pressure (Refs. 5 through 7), but on an investigational basis.

In the literature reviewed, an investigation of one device in a series of 650 patients (Ref. 2) showed an average infection rate of 2.1 percent and an average device failure rate of 8 percent. Device failures were due either to faulty installation or to brain herniation. In this investigation, the monitoring device was not left in place more than 20 days, and 5 days use was typical. In another study of a different device involving 27 patients, the pressure monitoring device was left in place for longer periods of time, with 14 days being a typical period and the extreme being 41 days (Ref. 4).

Based on the Panel recommendation and the references listed below, the Commissioner is proposing that the intracranial pressure monitoring device for short-term monitoring be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFC20), Rm. 465, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m. Monday through Friday, except on Federal holidays:

1. Hanlon, K., "Description and Uses of Intracranial Pressure Monitoring," *Heart and Lung*, 5:277282, 1976.

2. Winn, H. R. et al., "Intracranial Subarachnoid Pressure Recording: Experience With 650 Patients," *Surgical Neurology*, 8:41-47, (1977).

3. Vries, J. K. et al., "A Subarachnoid Screw for Monitoring Intracranial Pressure," *Journal of Neurosurgery*, 39:416-419, 1973.

4. Tindal, G. T. et al., "Current Methods for Monitoring Patients with Head Injury," *Clinical Neurosurgery*, 19:98-120, 1972.

5. Dorsch, N. W. C. and L. Symon, "A Practical technique for Monitoring Extradural Pressure," *Journal of Neurosurgery*, 42:249-257, 1975.

6. Zervas, N. T. et al., "A Pressure-Balanced Radio-Telemetry System for the Measurement of Intracranial Pressure," *Journal of Neurosurgery*, 47:899-911, 1977.

7. Yoneda, S. et al., "Continuous Measurement of Intracranial Pressure with SFT: Clinical Experience," *Surgical Neurology*, 4:289-295, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1620 as follows:

§ 882.1620 Intracranial pressure monitoring device.

(a) *Identification.* An intracranial pressure monitoring device is a device used for short term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32882 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1025]

MEDICAL DEVICES

Classification of Percussors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying percussors into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of percussors:

1. Identification: A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for classification: A percussor is a simple nonpowered device, usually a rubber tipped hammer, used as an aid in physicial examination. Because the characteristics of the device are obvious, and its functional capability is easily determined by examination of the device, the Panel recommends that the device be classified into class I (general controls) and that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel members are familiar with devices of this type because they are used in routine physical examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the percussor be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that the percussor be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing practice regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360C 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1700 as follows:

§ 882.1700 Percussor.

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32883 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1026]

MEDICAL DEVICES

Classification of Pinwheels

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pinwheels into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendations with respect to the classification of pinwheels:

1. Identification: A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that the pinwheel be classified into class I (general controls) because it is a simple mechanical device which contains no hazards to health and which requires no special material or properties.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this deivice.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pinwheels be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1750 as follows:

§ 882.1750 **Pinwheel.**

(a) *Identification.* A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies-of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32884 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1027]

MEDICAL DEVICES

Classification of Ocular Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ocular plethysmographs into class III (premarket approval). the FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A notice elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. the Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ocular plethysmographs:

1. Identification: An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restriction on blood flow in a carotid artery).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reaons for recommendation: The Panel recommends that the ocular plethysmograph be classified into class III (premarket approval) because the device is used to detect the life-threatening condition that occurs when the brain does not receive adequate blood flow through a carotid artery. Also, the Panel believes that it is not possible to establish an adequate performance standard for this device. The information derived from the ocular plethysmograph may be used to screen patients for the more risky diagnostic procedure of carotid angiography (an invasive radiological technique involving injection of radiopaque material into the patient's arterial system to detect arterial disorders such as carotid artery occlusion). If the ocular plethysmograph produces a false positive result, an unnecessary carotid angiography procedure may be performed; however, a false negative result could result in the failure to detect carotid artery occlusion. the Panel believes that the reliability of ocular plethysmograph measurements in detecting the presence or absence of carotid artery occlusion has not been sufficiently demonstrated and that the device should, therefore, be subject to premarket approval to assure satisfactory performance of the device and thus to provide reasonable assurance of its safety and effectiveness.

4. Summary of data on which the recommendation is based: the Panel members based their recommendation on their clinical experience and their knowledge of the techniques used in ocular plethysmography.

5. Risks to health: a. Eye injury. Excessive pressure can damage the eye.

b. Misdiagnosis. The device may misdiagnose the presence or absence of carotid artery occclusion because of a poor relationship between pulsatile arterial blood flow changes and the degree of occlusion.

c. Infection. Eye cups that are not sterile can cause infections.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that ocular plethysmographs be classified into class III (premarket approval).

The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, especially if practitioners rely upon the information derived from the device to diagnose carotid artery occclusion. Furthermore, the device is for a use (screening for carotid angiography) which is of substantial importance in preventing impairment of human health. The Commissioner believes that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard that will provide such assurance. Therefore, the Commissioner is proposing that ocular plethysmographs be classified into class III (premarket approval).

The Commissioner has obtained additional data and information describing the application of ocular plethysmographic devices. There are two techniques used to diagnose an occlusion of the carotid artery: pulse delay detection and ophthalmic artery pressure measurement.

The pulse delay detection technique gives inaccurate diagnostic information when a patient has symmetrical bilateral occlusive disease of the carotid artery, disease of the eye globe, occlusive disease of the ophthalmic artery, or arteriosclerotic lesions that do not alter blood flow (Ref. 1). A study of 210 carotid arteries reported that this technique is 81 percent accurate when results from it are compared with those of carotid angiography (Ref.1). In another study involving 936 caparisons with results of carotid angiography, 7 percent of diagnoses were false negatives (significant occlusion that was not detected), and 8 percent of diagnoses were false positives (patients without significant occlusive disease were indicated by the technique to have occlusion) (Ref. 2).

The systolic ophthalmic artery pressure measurement technique causes a transient elevation of intraocular pressure that is 400 percent to 500 percent above normal (Refs. 3 through 5). This technique does not accurately diagnose patients with less than 70 percent occlusion of the carotid artery (Ref. 1). Greater sensitivity is reported when the carotid artery is compressed manually (Refs. 1 and 3). However, because the carotid compression technique presents risks of cardiac arrhythmia or neurologic deficit, adequate assurance of safety is not possible.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday, except on Federal Holidays:

1. Dean, R. and J. Yao, "Hemodynamic Measurements in Peripheral Vascular Disease," *Current Problems in Surgery*, 12:52-56, 1976.

2. Karchner et al., "Oculoplethysmography: An Adjunct to Arteriography in the Diagnosis of Extracranial Carotid Occlusive Disease," *American journal of Surgery*, 132:728-732, 1976.

3. Gee, W. et al., "Measurement of Collateral Cerebral Hemispheric Blood Pressure by Ocular Pneumoplethysmography," *American Journal of Surgery*, 130:121-127, 1975.

4. Gee, W. et al., "Simultaneous Bilateral Determination of the Systolic Pressure of the Ophthalmic Arteries by Ocular Pneumoplethysmography," *Investigative Ophthalmology and Visual Science*, 16:86-89, 1977.

5. Gee, W. et al., "Noninvasive Diagnosis of Carotid Occlusion by Ocular Pneumoplethysmography," *Stroke*, 7:18-21, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1790 as follows:

§ 882.1790 Ocular plethysmograph.

(a) *Identification.* An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32885 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1028]

MEDICAL DEVICES

Classification of Rheoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rheoencephalographs into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of rheoencephalographs:

1. Identification: A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the rheoencephalograph be classified into class III because satisfactory performance has never been demonstrated, and the Panel believes that it is not possible to establish an adequate performance standard for this device. Although electrical standards would be sufficient to control electric shock hazard, the device design presents an inherent risk of misdiagnosis of cerebral circulatory status. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members are familiar with the literature on this device. Some of the panel members have witnessed its clinical application. Dr. William Jarzembski, one of the Panel members, provided some detailed information concerning his research on this device.

5. Risks to health: a. Erroneous clinical conclusions. The device may indicate that cerebral circulation is normal, when in fact it may be very abnormal.

b. Electrical shock. Excessive current could cause injury, and malfunction of the device could result in an electrical shock.

c. Skin reaction. The electrode materials and conductive media may irritate the skin.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that rheoencephalographs be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of cranial impedance techniques (rheoencephalograph) to measure cranial blood flow. Some of the literature states that this measurement is feasible but has not been sufficiently refined to be practical (Refs. 1 through 3). However, Hill et al. (Ref. 4) assert that the theoretical basis for this measurement is erroneous and that the pulsatile signal obtained from these devices is due to an unrelated phenomenon.

The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if practitioners rely upon the information derived from the device to diagnose conditions which result in abnormal cerebral blood flow. The Commissioner concurs that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays:

(1) Jarzembski, W. B., "Pathological Implications of Transcranial Impedence Change," (prepublication draft).

(2) Jarzembski, W. B., "Evaluation of Specific Cerebral Impedance and Cerebral Current Density," *Annals of New York Academy of Science*, 170:476-490, 1970.

(3) Geddes, L. A. and H. E. Hoff, "The Measurement of Physiologic Events by Electrical Impedance," *American Journal of Medical Electronics*, 3:16-27, 1964.

(4) Hill, R. V. et al., "Electrical Impedance Plethysmography: A Critical Analysis," *Journal of Applied Physiology*, 22:161-68, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1825 as follows:

§ 882.1825 Rheoencephalograph.

(a) *Identification.* A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32886 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1029]

MEDICAL DEVICES

Classification of Physiological Signal Amplifiers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physiological signal amplifiers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of physiological signal amplifiers:

1. Identification: A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the physiological signal amplifier be classified into class II (performance standards) to assure that the device is electrically safe because the amplifier makes a low-resistance connection with the patient and there is a hazard of dangerous electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and their knowledge of these devices.

5. Risks to health: Electrical shock: Leakage of electric current can produce dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal amplifier be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1835 as follows:

§ 882.1835 Physiological signal amplifiers.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32887 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1030]

MEDICAL DEVICES

Classification of Physiological Signal Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulaton classifying physiological signal conditioners into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of physiological signal conditioners:

1. Identification: A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to assure a sufficient degree of accuracy for its intended function. Also, electrical safety standards are needed to prevent excessive leakage current when used with other electrical hospital equipment. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and indicate that these hazards are widely recognized.

5. Risks to health: a. Electrical shock: Use of this device with other hospital equipment might result in leakage current and electrical shock of the patient.

b. Inaccurate diagnosis. Inadequate accuracy or distortion of the physiological signal could result in false information.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new §882.1845 as follows:

§ 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hous of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32888 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1031]

MEDICAL DEVICES

Classification of Physiological Signal Telemetry Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physiological signal telemetry systems into class II (perform-

ance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of physiological signal telemetry systems:

1. Identification: A physiological signal telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring physiological signals by means of radio or telephone transmission systems.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to ensure that the device performs with a sufficient degree of accuracy. The Panel believes that electrical safety standards are also needed to prevent excessive leakage current when the device is used with other electrical hospital equipment. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device and state that users are familiar with the identified risks to health presented by this device.

5. Risks to health: a. Electrical shock: Use of this device with other hospital equipment might cause excessive leakage current that would be hazardous to the patient.

b. Inaccurate diagnosis. Inadequate accuracy or distortion of the physiological signal could result in false information and, therefore, inaccurate diagnosis.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal telemetry system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1855 as follows:

§ 882.1855 Physiological signal telemetry system.

(a) *Identification.* A physiological signal telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring physiological signals by means of radio or telephone transmission systems.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32889 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1032]

MEDICAL DEVICES

Classification of Evoked Response Electrical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response electrical stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response electrical stimulators:

1. Identification: An evoked response electrial stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because its electrical current may cause burns to the body if the output parameters are not controlled. The Panel believes that the device is safe when the electrical output is limited according to established parameters. The Panel believes that performance standards can be established to control the risks of this device and that the provisions of general controls are not sufficient to assure its safety and effectiveness. The Panel believes that performance standards will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which recommendation is based: The Panel members based their recommendation on their clinical experience and judgment. Electrical stimulators for evoked response measurements have been widely used.

5. Risks to health: a. Local burns. Improper electrode surface area or excessive current can cause burns.

b. Electrical shock. Leakage current can produce electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response electrical stimulator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1870 as follows:

§ 882.1870 Evoked respose electrical stimulators.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to be patient by means of skin electrodes for the purpose of measuring the evoked response.

(b) *Classification:* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32890 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1033]

MEDICAL DEVICES

Classification of Evoked Response Mechanical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response mechanical stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response mechanical stimulators:

1. Identification: An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendations: The Panel recommends that this device be classified into class II (performance standards) to protect the patient against the possibility of electrical shock hazard from an external electrical source. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience and scientific knowledge regarding the problems posed by electrical devices.

5. Risks to health: Electrical shock: Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response mechanical stimulator be classified into class II (performance standards). However, he is aware that evoked response averaging techniques require the stimulator to be synchronized with the recording device to permit proper interpretation of the evoked response record. The Commissioner believes, therefore, that the functional characteristics of this device are important to its effectiveness and should also be addressed in a standard. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1),

the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1880 as follows:

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimuli or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32891 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1034]

MEDICAL DEVICES

Classification of Evoked Response Photic Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response photic stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response photic stimulators:

1. Identification: An evoked response photic stimulator is a device used to apply a brief light stimulus to a patient's eye for use in evoked response measurements or electroencephalogram activation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the evoked response photic stimulator be classified into class II (performance standards) because an excessively intensive light source may damage the retina, and the possibility of flashlamp implosion requires that protection be provided. Also, the Panel believes that electrical safety standards are needed to eliminate shock hazards, especially when the device is used with other electrical equipment. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectivenss of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and state that these hazards are widely recognized.

5. Risks to health: a. Retinal damage. An intense light source could burn the retina.

b. Eye and face injury. Glass from an imploding lamp could be projected toward the face.

c. Electrical shock. Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response photic stimulator be classified into class II (performance standards). In addition to the hazards cited by the Panel, the Commissioner believes that this device has performance characteristics which should be controlled to insure that it performs its intended function. Failure of the device to perform satisfactorily can result in erroneous diagnosis of various neurological disorders. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectivenss of the device. The Commissioner also believs that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1890 as follows:

§ 882.1890 Evoked response photic stimulator.

(a) *Identification.* An evoked response photic stimulator is a device used to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32892 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1035]

MEDICAL DEVICES

Classification of Evoked Response Auditory Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response auditory stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response auditory stimulators:

1. Identification: An evoked response auditory stimulator is a device that produces a sound stimulus for use during evoked response measurements or electroencephalogram activation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Pannel recommendations that evoked response auditory stimulators be classified into class II (performance standards) because the device applies to the ear acoustic energy which should be carefully limited to prevent hearing loss and other injury, and the performance of the device should meet standards to ensure that an accurate result is obtained. Electric shock hazards are present with this device and should be controlled by standards. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Audiometry and evoked response measurements are used clinically on a routine basis. The Panel members based their recommendation on their clinical experience and their knowledge of this technique.

5. Risks to health: a. Hearing damage: Excessive sound intensity can injure the ear.

b. Electrical shock: Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response auditory stimulator be classified into class II (performance standards). In addition to the risks to health cited by the Panel, the Commissioner believes that there are risks associated with the fact that a failure of this device to perform accurately is not necessarily apparent to the physician and may result in failure to detect hearing loss. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissionr also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1900 as follows:

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification.* An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32893 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1036]

MEDICAL DEVICES

Classification of Ultrasonic Scanner Calibration Test Blocks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic scanner calibration test blocks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ultrasonic scanner calibration test blocks:

1. Identification: An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: This device consists of a block of material of known thickness and composition that is used to calibrate ultrasonic scanning devices. Because the device makes no contact with the patient, the Panel believes that it does not present a risk to the patient and, therefore, the Panel recommended that it be classified into class I (general controls).
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on experience with ultrasonic scanning devices.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ultrasonic scanner calibration test blocks be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1925 as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification.* An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32894 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1037]

MEDICAL DEVICES

Classification of Tremor Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tremor trnasducers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tremor transducers:

1. Identification: A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendations: Tremor transducers are used to quantify what would otherwise be a subjective estimate. The physiological measurement which is performed does not need to be precise. However, because the device is electrically powered, the Panel recommends that it be classified into class II (performance standards) to assure electrical safety. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members believe that the need to control electrical hazards is well known.
5. Risks to health: Electrical shock: Excessive leakage current could injure the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the tremor transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1950 as follows:

§ 882.1950 Tremor transducer.

(a) *Identification.* A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug

Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32895 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1038]

MEDICAL DEVICES

Classification of Skull Plate Anvils

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull plate anvils into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull plate anvils:

1. Identification: A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the skull plate anvil be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is used only as a tool to alter skull plates and does not come into contact with the patient. The Panel believes that the device is constructed with generally acceptable materials and presents no health hazards.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and the conditions of its use:

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skull plate anvil be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 by adding new Subpart E—Neurological Surgical Devices—consisting at this time of § 882.4030, to read as follows:

Subparts C and D—[Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification.* A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heating of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32896 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1039]

MEDICAL DEVICES

Classification of Ventricular Cannulas

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventricular cannulas into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification

Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventricular cannulas:

1. Identification: A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection This device is frequently referred to as a ventricular needle.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the ventricular cannula be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The ventricular cannula is a simple device that is frequently used in the practice of neurosurgery. The Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device, which is routinely used in neurosurgery.

5. Risks to health: (a) Tissue or blood vessel damage. Brain tissue or intracranial blood vessels may be damaged if the ventricular cannula has sharp or uneven edges or burrs. (b) Infection. Since the cannula is inserted into the brain, infection may occur if the cannula is not sterile.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ventricular cannula be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4060 as follows:

§ 882.4060 Ventricular cannula.

(a) *Identification.* A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32897 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1040]

MEDICAL DEVICES

Classification of Ventricular Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventricular catheters into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventricular catheters:

1. Identification: A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

2. Recommend classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summay of reasons for recommendation: The Panel recommends that the ventricular catheter be classified into class II (performance standards) because the Panel believes that standards are necessary to control the surface properties of the catheter to avoid injury and to insure that the catheter can be sterilized. The Panel believes that the catheter should be constructed of materials that are suitable for chronic (long term) implantation because it is often necessary for the device to remain in the patient for an extended period of time. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device.

5. Risks to health: (a) Tissue or blood vessel damage: Brain tissue or intracranial blood vessels may be damaged if the ventricular catheter has sharp or uneven edges or burrs. (b) Infection: Since the catheter inserted into the brain, infection may occur if the catheter is not sterile.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ventricular catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4100 as follows:

§ 882.4100 Ventricular catheter.

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32898 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1041]

MEDICAL DEVICES

Classification of Neurosurgical Chairs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical chairs into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical chairs:

1. Identification: A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical chair be classified into class I because the device is used only to position and support the patient during surgery, and therefore general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the user can control the possible hazard of chair position instability through proper maintenance. The Panel does not believe that this device requires a performance standard to control the identified risks to health.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: Chair position instability: Chair position instability may allow sudden movement of the patient during the operation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical chair be classifed into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4125 as follows:

§ 882.4125 Neurosurgical chair.

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32899 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1042]

MEDICAL DEVICES

Classification of Scalp Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scalp clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of scalp clips:

1. Identification: A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the scalp clip be classified into class II (performance standards) because performance standards are necessary to control the amount of pressure applied by the clip to the point of contact. These devices are used to clip temporally tissue or blood vessels during surgery of the head. The clips are not left in the patient but are removed upon completion of the surgery. The Panel believes that general controls will not provide sufficient control over the amount of pressure applied by the clip. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Necrosis of the scalp: Injury to the scalp tissue may occur if the clip applies excessive pressure at the point of contact. (b) Failure of hemostasis: The pressure of the clip must be sufficient to prevent bleeding in the area applied

PROPOSED CLASSIFICATION

The commissioner agrees with the Panel's recommendation and is proposing that the scalp clip be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701 (a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4150 as follows:

§ 882.4150 Scalp clip.

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32900 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1043]

MEDICAL DEVICES

Classification of Aneurysm Clip Appliers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aneurysm clip appliers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of aneurysm clip appliers:

1. Identification: An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the aneurysm clip applier be classified into class II (performance standards) because it is a specialized surgical tool that must be very reliable. Its design may be quite simple, but a high degree of precision is needed to minimize the risk associated with clipping intracranial aneurysms. Although various types of this device that are quite satisfactory have been marketed, the Panel believes that performance standards are needed to ensure the degree of reliability, precision, and suitability necessary for adequate safety. The Panel believes that general controls will not provide sufficient control over these characteristics. Elsewhere in this issue of the FEDERAL REGISTER, the Panel is recommending that aneurysm clips be classified into class II and that they be given a high priority for development of standards. The Panel also recommends that the development of performance standards for the aneurysm clip applier be given a high priority because of the importance of the device to safe aneurysm clip surgery. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information is available to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with the device, which is frequently used in aneurysm surgery.

5. Risks to health: (a) Blood vessel injury: If the device has sharp edges, the edges can cut a blood vessel. Mechanical action of the clip applier can shear a blood vessel. (b) Hemorrhage: Failure of the device to properly control the clip can result in a poorly applied clip that allows the aneurysm to leak. (c) Death: Improper manipulation of the clip can result in a rupture of the aneurysm, which is likely to be fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is pro-

posing that the aneurysm clip applier be classified into class II (performance standard). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4175 as follows:

§ 882.4175 Aneurysm clip applier.

(a) *Identification.* An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32901 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1044]

MEDICAL DEVICES

Classification of Clip Forming/Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip forming/cutting instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of clip forming/cutting instruments:

1. Identification: A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the clip forming/cutting instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A clip forming/cutting instrument is a simple device used to cut pieces of wire in order to make tissue clips for use in surgery. The Panel believes that the device presents no health hazards.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity and clinical experience.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip forming/cutting instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4190 as follows:

§ 882.4190 Clip forming/cutting instrument.

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32902 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1045]

MEDICAL DEVICES

Classification of Clip Removal Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip removal instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of clip removal instruments:

1. Identification: A clip removal instrument is a device used to remove surgical clips from the patient.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the clip removal instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that this simple device presents no health hazards.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip removal instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4200 as follows:

§ 882.4200 Clip removal instrument.

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32903 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1046]

MEDICAL DEVICES

Classification of Clip Racks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip racks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of clip racks:

1. Identification: A clip rack is a device used to hold or store surgical clips during surgery.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the clip rack be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is used for storing clips and does not come into direct contact with the patient.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip rack be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4215 as follows:

§ 882.4215 Clip rack.

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during surgery.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours

of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32904 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882

[Docket No. 78N-1047]

MEDICAL DEVICES

Classification of Cryogenic Surgical Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cryogenic surgical devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cryogenic surgical devices:

1. Identification: A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Sumary of reasons for recommendation: The Panel recommends that cryogenic surgical devices be classified into class II (performance standards) because the temperature of the device probe must be controlled assure satisfactory performance. The Cryogenic surgical device is used to destroy selectively very small parts of the brain or spinal cord. The size of the destroyed area is determined by the temperature of the tip of the device probe, and the destroyed area must be precisely controlled to minimize the risk of causing a neurologic deficit or of failing to obtain a good therapeutic result. The Panel believes that general controls will not provide sufficient control over these characteristics. The panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Inappropriate size lesions. Inaccurate control of the temperature can result in a lesion that is either too large or too small. A lesion that is too small does not produce a good therapeutic result and a lesion that is too large may cause a neurological deficit. (b) Electrical shock. Leakage current from the thermal element or from the monitoring element can injure the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cryogenic surgical device be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4250 as follows:

§ 882.4250 Cryogenic surgical device.

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32905 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1048]

MEDICAL DEVICES

Classification of Dowel Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dowel cutting instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of dowel cutting instruments:

1. Identification: A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the dowel cutting instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The dowel cutting instrument is a very simple device that has no inherent hazard.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the dowel cutting instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4375 as follows:

§ 882.4275 · Dowel cutting instrument.

(a) *Identification.* A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32906 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1049]

MEDICAL DEVICES

Classification of Manual Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual drills, burrs, trephines, and their accessories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of manual drills, burrs, trephines, and accessories:

1. Identification: Manual drills, burrs, trephines, and their accessories are manually operated bone cutting and drilling instruments that are used without a power source.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that manual drills, burrs, trephines, and their accessories be classified into class II to require guards that will prevent the device tips from plunging into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these devices, which are routinely used in neurosurgical procedures.
5. Risks to health: Penetration of brain tissue: The device can cause brain injury by plunging into the brain after entry through the skull.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that manual drills, burrs, trephines, and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4300 as follows:

§ 882.4300 **Manual drills, burrs, trephines, and their accessories.**

(a) *Identification.* Manual drills, burrs, trephines, and their accessories are manually operated bone cutting and drilling instruments that are used without a power source.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32907 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1050]

MEDICAL DEVICES

Classification of Powered Compound Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered compound drills, burrs, trephines, and their accessories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classfying these devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered compound drills, burrs, trephines, and their accessories:

1. Identification: Powered compound drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that use a power source and employ a clutch mechanism to prevent the instrument's tip from plunging into the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered compound drills, burrs, trephines and their accessories be classified into class II (performance standards) because standards are necessary to control the performance of the clutch used to prevent the device from accidentally plunging into the brain. Failure of the clutch mechanism could result in brain damage if the tip accidentally plunges into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with these devices; they are widely used and the hazards are well known.

5. Risks to health: Penetration of brain tissue: Accidental penetration of brain tissue can cause brain injury if the clutch fails.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that powered compound drills, burrs, trephines, and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4305 as follows:

§ 882.4305 Powered compound drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered compound drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that use a power source and employ a clutch mechanism to prevent the instrument's tip from plunging into the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32908 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1051]

MEDICAL DEVICES

Classification of Powered Simple Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered simple drills, burrs, trephines, and their accesories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become ef-

fective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered simple drills, burrs, trephines, and their accessories:

1. Identification: Powered simple drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used with a power source but without a clutch mechanism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered simple drills, burrs, trephines, and their accessories be classified into class II (performance standards) because standards are necessary to assure safe design. The Panel believes that guards are needed to prevent the tool cutting tip from accidentally plunging into the brain and that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with these devices. The devices are widely used, and the hazards are well known.

5. Risks to health: Penetration of brain tissue: The tip of the cutting tool can accidentally plunge into the brain tissue causing brain injury if the device lacks guards to prevent plunging.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that powered simple drills, burrs, trephines, and their accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4310 as follows:

§ 882.4310 Powered simple drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered simple drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used with a power source but without a clutch mechanism.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32909 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1052]

MEDICAL DEVICES

Classification of Drill Handpieces (Brace)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulations classifying drill handpiece (brace) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A Proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of drill handpieces (brace):

1. Identification: A drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that drill handpieces (brace) be classified into class II (performance standards) because a standard is needed that requires the device to have a guard that prevents the tip of the drill from being accidentally plunged into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the drill handpiece. These are common surgical tools that have been used by neurosurgeons for many years.

5. Risks to health: Penetration of brain tissue: The drill tip can accidentally plunge into the brain causing brain injury.

PROPOSED CLASSIFICATION

The Commissioner ageees with the Panel's recommendation and is pro-

posing that the drill handpiece (brace) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4325 as follows:

§ 882.4325 **Drill handpiece (brace).**

(a) *Identification.* A drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32910 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1053]

MEDICAL DEVICES

Classification of Electric Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulations classifying electric drill motors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATED: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electric drill motors:

1. Identification: An electric drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electric drill motors be classified into class II (performance standards) because performance standards are necessary to prevent excessive current leakage and electrical shock hazards. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the device. These devices have been used for many years and are very familiar to the Panel members.

5. Risks to health: (a) Electrical shock: The patient or the physician may receive an electrical shock from the device. (b) patient injury: If the device is unwieldy, poorly balanced, or too heavy, the physician may be unable to control it, and the patient may be injured.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that electric drill motors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposed to amend Part 882 in Subpart E by adding new § 882.4360 as follows:

§ 882.4360 **Electric drill motor.**

(a) *Identification.* An electric drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before Janurary 29, 1979, submit to the Hearing Clerk (HFA-305). Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32911 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1054]

MEDICAL DEVICES

Classification of Pneumatic Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pneumatic drill motors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pneumatic drill motors:

1. Identification: A pneumatic drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pneumatic drill motors be classified into class II (performance standard) because the method of exhausting the gas used to power the device and the method of pressure regulation used with the device should be controlled to assure safety. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these device. These devices are routinely used and have been in use for many years.

5. Risks to health: (a) Air emboli: The gas which is exhausted from the drill motor may cause emboli if directed toward the wound site: (b) Infection and contamination: The exhaust gas may carry contaminants into the wound site. (c) Patient injury: The device may explode, and the patient may be injured if the pressure regulation fails.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that pneumatic drill motors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4370 as follows:

§ 882.4370 **Pneumatic drill motor.**

(a) *Identification.* A pneumatic drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32912 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1055]

MEDICAL DEVICES

Classification of Radiofrequency Lesion Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radiofrequency lesion generators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation

with respect to the classification of radiofrequency lesion generators:

1. Identification: A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the radiofrequency lesion generator be classified into class II (performance standards) because the electrical characteristics of the lesion generator must be controlled to assure satisfactory performance. The radiofrequency lesion generator is used to selectively destroy very small parts of the brain, spinal cord, or other tissue. The size of the destroyed area must be precisely controlled to minimize the risk of causing a neurological deficit or of failing to obtain a good therapeutic result. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience using these devices.

5. Risks to health: (a) Excessive destruction of normal tissue. Inaccurate or unreliable control of the lesioning current can produce an excessively large lesion that may produce a neurological deficit in the patient. (b) Failure to produce lesions of appropriate size. Inaccurate or unreliable control of the lesioning current can result in a lesion that is too small to produce a therapeutic result. (c) Electrical shock. Excessive leakage current can injure the patient. (d) Burns. Improper design of the return (inactive) electrode can cause burns.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the radiofrequency lesion generator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4400 as follows:

§ 882.4400 Radiofrequency lesion generator.

(a) *Identification.* A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32913 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1057]

MEDICAL DEVICES

Classification of Neurosurgical Headrests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical headrests into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical headrests:

1. Identification: A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical headrest be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device because of the simplicity of the device design. The Panel believes that performance standards are not necessary for the neurosurgical headrest because the user can control the risks to health identified for this device by carefully positioning the patient's head.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device.

5. Risks to health: Eye or ear damage. If the physician improperly positions the neurosurgical headrest, it may place excessive pressure on the patient's eye or ear.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical headrest be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4440 as follows:

§ 882.4440 Neurosurgical headrest.

(a) *Identification.* A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32914 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1058]

MEDICAL DEVICES

Classification of Neurosurgical Head Holder (Skull Clamp)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the neurosurgical head holder (skull clamp) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of the neurosurgical head holder (skull clamp):

1. Identification: A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold the head and neck in a particular position during surgical procedures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical head holder (skull clamp) be classified into class II (performance standards) to prevent penetration of the skull clamp points into the brain. The Panel believes that performance standards are necessary to ensure that the locking mechanism is suitable and to ensure that corrosion resistant materials are used. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.

5. Risks to health: Patient injury. Excessive spring pressure or improper skull clamp pin design may allow penetration of the pin points into the brain. Premature release of pins may result in a sudden movement of the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical head holder (skull clamp) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat., 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4460 as follows:

§ 882.4460 Neurosurgical head holder (skull clamp).

(a) *Identification.* A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold the head and neck in a particular position during surgical procedures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32915 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1059]

MEDICAL DEVICES

Classification of Cranioplasty Material Forming Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranioplasty material forming instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regula-

tion based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Gerogia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cranioplasty material forming instruments:

1. Identification: Cranioplasty material forming instruments are rollers used in the preparation and forming of cranioplasty (skull repair) materials.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the craniplasty material forming instrument be classified into class I because general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device. The device is a simple roller that does not come into direct contact with the patient.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and its use.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cranioplasty material forming instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4500 as follows:

§ 882.4500 Cranioplasty material forming instrument.

(a) *Identification.* Cranioplasty material forming instruments are rollers used in the preparation and forming of cranioplasty (skull repair) materials.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32916 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1061]

MEDICAL DEVICES

Classification of Microsurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microsurgical instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of microsurgical instruments:

1. Identification: A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that microsurgical instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The Panel believes that the hazards associated with these devices depend primarily upon the skill of the user.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that these devices are common surgical instruments which have been in use for many years.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that microsurgical instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.45.25 as follows:

§ 882.4525 Microsurgical instrument.

(a) *Identification.* A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), and Drug Ad-

ministration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32917 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1062]

MEDICAL DEVICES

Classification of Nonpowered Neurosurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonpowered neurosurgical instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nonpowered neurosurgical instuments:

1. Identification: A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used in neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered surgical instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these simple devices.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that these devices are common surgical instruments which have been in routine use for many years.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the nonpowered neurosurgical instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4535 as follows:

§ 882.4535 Nonpowered neurosurgical instruments.

(a) *Identification.* A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be see in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32918 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1063]

MEDICAL DEVICES

Classification of Shunt System Implantation Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying shunt system implantation instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of shunt system implantation instruments:

1. Identification: A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that shunt system implantation instruments be classified into class I because general controls are sufficient to provide reasonable assurance of their safety and effectiveness. Although this device has a special purpose, it is a simple hand instrument that has no inherent hazards associated with it.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their own surgical experience.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that shunt system implantation instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4545 as follows:

§ 882.4545 Shunt system implantation instrument.

(a) *Identification.* A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32919 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1064]

MEDICAL DEVICES

Classification of Stereotaxic Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stereotaxic instruments into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of stereotaxic instruments:

1. Identification: A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that stereotaxic instruments be classified into class II (performance standards) because of the importance of ensuring the rigidity, precision, and accuracy of this instrument. In addition, the patient may be injured if the probe is not precisely positioned or if the instrument is not stable. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device, which has been used by neurosurgeons for many years.

5. Risks to health: Tissue damage. Improper calibration of the device could result in surgical error and damage to brain tissues. Instability of the device or its base or inadequate rigidity could result in tissue damage if the device is moved suddenly or becomes miscalibrated. If the device does not hold the skull properly in place, the head could move and tissue damage from miscalibration could result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the panel recommendation and is proposing that the stereotaxic instrument be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4560 as follows:

§ 882.4560 Stereotaxic instrument.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning

probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305) Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32920 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1065]

MEDICAL DEVICES

Classification of Leukotomes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying leukotomes into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of leukotomes:

1. Identification: A leukotome is a device used to cut sections out of the brain.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the leukotome be classified into class I because general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience and judgment.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the leukotome be classified into class I (general controls) with no exemptions because the Commissioner believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4600 as follows:

§ 882.4600 **Leukotome.**

(a) *Identification.* A leukotome is a device used to cut sections out of the brain.

(b) *Recommended classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32921 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1066]

MEDICAL DEVICES

Classification of Neurosurgical Suture Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical suture needles into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical suture needles:

1. Identification: A neurosurgical suture needle is a needle used in suturing during

neurosurgical procedures or in the repair of nervous tissue.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: the Panel recommends that neurosurgical suture needles be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device is a very simple device, and the materials which have been used in the needles have all been generally acceptable.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that this device is essentially equivalent to other suture needles that have been used for many years. The neurosurgeon members have had extensive experience with such suture needles.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical suture needle be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4650 as follows:

§ 882.4650 Neurosurgical suture needle.

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32922 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1067]

MEDICAL DEVICES

Classification of Cottonoid Paddies

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cottonoid paddies into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cottonoid paddies:

1. Identification: A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cottonoid paddies be classified into class II (performance standards) because the device may fragment and leave bits of cotton or fiber within the surgical wound and the Panel believes that performance standards are needed to control this hazard. The Panel also believes that cottonoid paddies should have radiopaque markers and suture tails in case the device is accidentally left within the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their familiarity and experience with this device, which is used frequently in neurosurgery. One of the Panel members stated that he has seen pieces of fiber from these devices in tissue specimens taken from patients.

5. Risks to health: (a) Foreign body materials in the patient. Fragmentation of the device, leaving fibers or fragments of cotton in the patient, may result in a foreign body reaction. (b) Tissue reaction. Scarring or other adverse tissue reactions may result if the material remains in the body or is toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cottonoid paddie be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4700 as follows:

§ 882.4700 Cottonoid paddies.

(a) *Identification.* A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in

brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32923 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1068]

MEDICAL DEVICES

Classification of Radiofrequency Lesion Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radiofrequency lesion probes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of radiofrequency lesion probes:

1. Identification: A radiofrequency lesion probe is a device that is connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to provide for a performance standard that minimizes the amount of coincidental destruction by the device of normal tissue. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: Excessive destruction of normal tissue. A probe that does not have the correct dimensions may cause unnecessary destruction of nervous tissue.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the radiofrequency lesion probe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4725 as follows:

§ 882.4725 Radiofrequency lesion probe.

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32924 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1069]

MEDICAL DEVICES

Classification of Skull Punches

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull punches into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides back-

ground information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull punches:

1. Identification: A skull punch is a device used to punch holes through a patients skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the skull punch be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and their knowledge of its design and the conditions of its use.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skull punch be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4750 as follows:

§ 882.4750 Skull punch.

(a) *Identification.* A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32925 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1070]

MEDICAL DEVICES

Classification of Self-Retaining Retractors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying self-retaining retractors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of self-retaining retractors:

1. Identification: A self-retaining retractor is a self-locking device used to hold the edges of a wound open during neurosurgery.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to protect against injuring the patient by sudden movement because of failure of the device's locking mechanism. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device, which is routinely used in neurosurgery.
5. Risks to health: Patient injury. Serious injury could result if the locking mechanism fails, allowing the retractor to collapse suddenly thereby disrupting the surgery.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the self-retaining retractor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4800 as follows:

§ 882.4800 Self-retaining retractor.

(a) *Identification.* A self-retaining retractor a is self-locking device used to hold the edges of a wound open during neurosurgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours

of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner, for Regulatory Affairs.

[FR Doc. 78-32926 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1071]

MEDICAL DEVICES

Classification of Manual Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comments a proposed regulation classifying manual rongeurs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of manual rongeurs:

1. Identification: A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the manual rongeur be classified into class II (performance standards) because of the need to control the variability in design and the high incidence of breakage of the rongeur jaws. Rongeurs that are represented to be of a particular design frequently vary considerably from the purported design and, in fact, may vary from year to year. The Panel believes that performance standards are needed to ensure that the thickness of the rongeur jaws and the material used in their construction are sufficient to prevent them from breaking. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: Residual foreign matter in patient. If rongeur jaws break because the metal is too thin or too brittle, pieces of metal may enter the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the manual rongeur be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4840 as follows:

§ 882.4840 Manual rongeur.

(a) *Identification.* A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner Regulatory Affairs.

[FR Doc. 78-32927 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1072]

MEDICAL DEVICES

Classification of Powered Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered rongeurs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of powered rongeurs:

1. Identification: A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered rongeur be classified into class II (performance standards) because of the need to control the variability in design and high incidence of breakage of the rongeur jaws. Rongeurs that are represented to be of a particular design frequently vary considerably from the purported design and, in fact, may vary from year to year. The Panel believes that performance standards also are needed to ensure that the thickness of the rongeur jaws and the material used in their construction are sufficient to prevent them from breaking. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: Residual foreign matter in patient. If the rongeur jaws break because the metal is too thin or too brittle, pieces of metal may enter the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the powered rongeur be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4845 as follows:

§ 882.4845 Powered rongeur.

(a) *Identification.* A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets, in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32928 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1073]

MEDICAL DEVICES

Classification of Skullplate Screwdrivers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skullplate screwdrivers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skullplate screwdrivers:

1. Identification: A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the skullplate screwdriver be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with these devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skullplate screwdriver be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4900 as follows:

§ 882.4900 Skullplate screwdriver.

(a) *Identification.* A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patients skull by screws.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hear-

ing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32929 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1074]

MEDICAL DEVICES

Classification of Sponges for Internal Use

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying sponges for internal use into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of sponges for internal use:

1. Identification: A sponge for internal use is a device used for absorbing blood or other fluids inside the body during surgery. It is not left in the body cavity after surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that sponges for internal use be classified into class II (performance standards) because they come into direct contact with the surgical wound and may contaminate the wound or produce a tissue reaction if the sponge materials are not suitable. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device, which has been used for absorption in surgical wounds for many years.

5. Risks to health: (a) Foreign body material in patients: If the sponge should fragment while in the patient, portions of the sponge may be left in the patient upon closure of the wound. (b) Tissue reaction: If not biocompatible, the sponge materials may cause adverse tissue reaction.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the sponge for internal use be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4925 as follows:

§ 882.4925 **Sponge (internal use).**

(a) *Identification.* A sponge for internal use is a device used for absorbing blood or other fluids inside the body during surgery. It is not left in the body cavity after surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32930 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1075]

MEDICAL DEVICES

Classification of Methyl Methacrylate for Aneurysmorrhaphy

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying methyl methacrylate for aneurysmorrhaphy (repair of aneurysms which are balloonlike sacs formed on blood vessels) into class II (performance standards). The FDA is also publishing the recommendation of the Neurosurgical Device Classification Panel that the device be classified into class II. The effect of classifing a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issure of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of methyl methacrylate for aneurysmorrhaphy:

1. Identification: Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or abliteration by aneurysm clip.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that methyl methacrylate for aneurysmorrhaphy be classified into class II (performance standards) because sufficient scientific and medical data are available to establish the safety and effectiveness of methyl methacrylate for this use. The Panel believes that premarket approval of this device is unnecessary because, although this product is implanted, methyl methacrylate has been used extensively for aneurysmorrhaphy and has been shown to be safe and effective. The hazards associated with the use of methyl methacrylate can be avoided by controlling its chemical composition and by following adequate preparation procedures. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive clinical experience in repairing aneurysms, their familiarity with the large amount of literature that has been published on aneurysm repair, and testimony from Dr. Shelley Chou, Professor of Neurosurgery at the University of Minnesota Medical School. Dr. Chou presented information pertaining to several chemical substances that have been employed for aneurysmorrhaphy. He pointed out the methyl methacrylate has been successfully used since 1956 for encasing aneurysms. The Panel was also informed that the American Society for Testing and Materials (ASTM) is presently working to develop standards for the formulation of methyl methacrylate that is to be used for neurosurgery.

5. Risks to health: (a) Immediate or delayed rupture of the aneurysm. Variations in the chemical composition and formulation of the polymer can result in an unpredictable setting time. (b) Injury to surrounding normal tissue. Variation in the composition of the material or the procedures used may result in excess heat that may injure adjacent tissue. (c) Tissue toxicity. Impurities in some formulations may be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that methyl methacrylate for aneurysmorrhaphy be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify methyl methacrylate for aneurysmorrhaphy into class II and has obtained additional data and information on the safety and effectiveness of this material. Methyl methacrylate has been used generally for various medical applications for approximately 40 years and has been used extensively for cranioplasty (repair of the skull) and in dentistry. This material has been employed since 1956 for encasement of intracranial aneurysms that cannot be treated by clipping or other more conventional means (Ref. 1). Hayes and Leaver reported in 1966 on 40 patients with aneurysms that were successfully treated without major complications with this material (Ref. 2). In 1968, Hammond reported on a total of 85 patients with 102 aneurysms that were encased with polymethyl methacrylate and noted two cases of hemorrhage from aneurysms that were not completely encased by the material (Ref. 3).

Although methyl methacrylate has been shown to produce an inflammatory reaction, in rabbit brain, that gradually lessens with time (Ref. 4), the material is generally regarded as safe for implantation (Ref. 5).

A temperature of 130° F may be produced by the polymerization of the methyl methacrylate, and concern has been expressed about the effect of this heat on structures adjacent to the aneurysm, such as blood vessels or the optic nerve. Hayes and Leaver, however, reported no evidence of such injuries and stated that the heat is easily handled by irrigating the aneurysm (Ref, 2). There is also an increase risk of rupturing the aneurysm during methyl methacrylate encasement because more dissection to free the aneurysm from the surrounding tissue is required for methyl methacrylate encasement than is required for clipping (Ref. 2).

The Commissioner believes that premarket approval is unnecessary for this implanted material because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the material for use in treating intracranial aneurysms. The Commissioner also believes that general controls alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Dutton, J. E. M., "Intracranial Aneurysm: A New Method of Surgical Treatment," *British Medical Journal*, 2:585-586, 1956.

2. Hayes, G. J. and R. C. Leaver, "Methyl Methyacrylate Investment of Intracranial Aneurysms," *Journal of Neurosurgery*, 25:79-80, 1966.

3. Hammon, W. M., "Intracranial Aneurysm Encasement," *Journal of Neurology, Neurosurgery and Psychiatry*, 31:524-547, 1968.

4. Tsuchiya, G., et al., "Reactions of Rabbit Brain and Peripheral Vessels to Plastic Used in Coating Arterial Aneurysms," *Journal of Neurosurgery*, 28:409-416, 1968.

5. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, Calif., pp. 8-4 and 14-2 to 14-32.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 by adding new Subpart F, including § 882.5030, to read as follows:

Subpart F—Neurological Therapeutic Devices

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.

(a) *Identification.* Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32931 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1076]

MEDICAL DEVICES

Classification of Biofeedback Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying biofeedback devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of biofeedback devices:

1. Identification: A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological paramenters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that biofeedback devices be classified into class II (performance standards) because they are electrically powered and are attached to patients by means of electrodes, thus exposing patients to risk of electrical shock. The Panel also believes that the device should be required to meet performance standards to assure that the device reliably measures the physiological parameter that it is intended to measure. The Panel notes that biofeedback has been reported to be useful for treating a variety of medical conditions, such as retraining muscles in paralyzed patients, treatment of stress and migraine headache, and reduction of blood pressure. The Panel recommends that the device's labeling include a warning stating that if the device is used in the diagnosis or treatment of disease, it should be used only by, or after consulting with, a physician. However, the Panel believes that use for nonmedical conditions (e.g., relaxation training) need not be under the supervision of a physician. The Panel believes that general controls will not provide sufficient control over the electrical safety and performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal knowledge of the devices and techniques used in biofeedback and on presentations made to the Panel by researchers in biofeedback. Dr. Charles Stroebel, Institute of Living, Hartford, Connecticut, and Dr. Kenneth Greenspan, New York State Psychiatric Institute, appeared before the Panel to present their opinions on biofeedback. Dr. Stroebel warned that indications and claims for biofeedback must be judged carefully because of the sensational reports in the lay press. Dr. Greenspan stressed that a patient should not be treated with biofeedback for medical conditions without an adequate medical examination because failure to diagnose some conditions may result in failure to institute appropriate treatment. Dr. Greenspan reported that stress and migraine headaches have been treated with 60 to 80 percent success after 1 year's followup. Dr. Greenspan also noted that he was concerned because of the lack of well-controlled studies for some of the investigational uses of biofeedback.

5. Risks to health: (a) Electrical shock. The patient may receive an electrical shock because the device is electrically powered and connected to the patient by means of electrodes. (b) Errors in treatment. If the device is used to treat medical conditions, the patient may become worse if the practitioner relies on the device and it does not perform properly.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that biofeedback devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner has also considered the Panel's recommendation that a warning label stating that if the device is used in the diagnosis or treatment of disease it should be used only by, or after consulting with, a physician, be affixed to the device or accompany the device. The Commissioner agrees with the Panel that biofeedback devices should be used for diagnosing or treating diseases or other medical conditions only by, or after consulting with, a physician. In the past, FDA has allowed unrestricted (over-the-counter) marketing of biofeedback devices only if no medical claims are made for the devices. The FDA does not regard a claim for use in relaxation training as a medical claim. The FDA regards a biofeedback device as misbranded if medical claims are made for the device and the device is not labeled for use only by or on the order of a physician or other licensed practitioner. The Commissioner intends to continue this policy for biofeedback devices and believes that this policy essentially satisfies the Panel's recommendation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5050 as follows:

§ 882.5050 Biofeedback device.

(a) *Identification.* A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fish-

ers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32932 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1077]

MEDICAL DEVICES

Classification of Bite Blocks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bite blocks into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bite blocks:

1. Identification: A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bite blocks be classified into class II (performance standards) because the design of the device and the material of which it is made must be adequate to prevent injury to the patient's teeth or gums and to prevent the patient from biting off a piece of the device and swallowing it. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device, which has been in use for many years.

5. Risks to health: (a) Injury to teeth and tongue. Improper design, excessively hard material, or improper application may permit injury to the patient's teeth or tongue, and the patient may aspirate or swallow teeth if the device causes them to be knocked out. (b) Aspiration of material. If the material is too weak, the patient may bite off a piece and aspirate or swallow it.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that bite blocks be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5070 as follows:

§ 882.5070 Bite Block.

(a) *Identification.* A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four Copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc.78-32933 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1078]

MEDICAL DEVICES

Classification of Intravascular Occluding Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intravascular occluding catheters into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intravascular occluding catheters:

1. Identification: An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels), of intracranial blood vessels.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the intravascular occluding catheter be classified into class III (premarket approval) because the device is used to treat severe and life-threatening conditions and presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that there is not sufficient information available to determine whether general controls will assure the safety and effectiveness of the device, nor is there sufficient scientific and medical data available so that performance standards can be established that will assure the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to ensure that manufacturers demonstrate satisfactorily the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that there are few data available on this device. Although the Panel members are aware of the use of this device in investigational programs, they believe that there is not enough information or data to demonstrate that its safety and effectiveness can be adequately controlled by means other than premarket approval.

5. Risks to health: (a) Infarction of nervous tissue. If the catheter is not controllable or if the balloon or tip should fail or unexpectedly come loose from the catheter, use of the device may cause infarction of nervous tissue (death of nervous tissue due to stoppage of circulation) and other serious injury to the brain and other nervous tissue. (b) Hemmorhage. The catheter or improper balloon inflation may injure a blood vessel and result in bleeding. (c) Thrombogenesis. Blood coagulation and clotting may result if the material of which the catheter is constructed is not compatible with blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intravascular occluding catheter be classified into class III (premarket approval). The device is used to treat severe and life-threatening conditions, and the Commissioner believes that it presents a potential unreasonable risk of illness or injury to the patient if the device should fail or if the practitioner is unable to control the ballon tip. Furthermore, the device is for a use (treatment of vascular malformations) which is of substantial importance in preventing impairment of human health. The Commissioner concurs that insufficient information exists to determine whether general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513. 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5150 as follows:

§ 882.5150 Intravascular occluding catheter.

(a) *Identification.* An intravascular occluding catheter is a catheter with an inflatable or detachable ballon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32934 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1079]

MEDICAL DEVICES

Classification of Carotid Artery Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carotid artery clamps into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of carotid artery clamps:

1. Identification: A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloon like sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attack directly by reducing the blood pres-

sure and blood flow to the aneurysm or other malformation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the carotid artery clamp be classified into class II (performance standards) because the performance of the device must be controlled to assure that the blood pressure reduction can be performed smoothly and because the material used in the device must be compatible with tissue. The clamp is used for occlusion of the carotid artery in patients with aneurysms that are difficult to attack directly. The Panel believes that biocompatible materials are necessary for this device because the clamp is implanted into the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device. This device has been in use for several decades to treat intracranial aneurysms.

5. Risks to health: (a) Brain injury. Poor control of the pressure reduction may result in stroke and injury to the brain. (b) Blood vessel injury. The carotid artery could be damaged if the control assembly does not easily couple with and uncouple from the clamp. (c) Tissue toxicity. The material used to construct the device may cause an adverse tissue reaction if it is not biocompatible.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the carotid artery clamp be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify the carotid artery clamp into class II (performance standards) and has obtained additional data and information on the device to determine if reasonable assurance of the safety and effectiveness of the device can be provided by performance standards.

Carotid artery occlusion is an established technique for the treatment of intracranial aneurysms, and the carotid artery clamp is an integral part of this treatment.

According to Tindall (Ref. 1), ligation (constriction) of the carotid artery as a treatment for intracranial aneurysms has a long history dating back to 1805. It was in the 1950's, however, that adjustable clamps allowing gradual occlusion of the artery were introduced (Refs. 1 and 2). With the advent of adjustable clamps, carotid ligation became more widely practiced in neurosurgery. Tindall believes that the clamp's ability to occlude the artery gradually has contributed to a lower incidence of neurological deficits in patients treated by carotid ligation. Several clamp designs have been introduced to further refine the technique of carotid ligation (Refs. 1 and 3).

Tindall lists indications and contraindications for carotid ligation and describes the procedure in detail (Ref. 1) Tindall also discusses complications of this technique. The most severe complication is the possibility of cerebral ischemia (insufficient blood flow to the brain). Tindall states that 38 patients out of a series of 220 (11.5 percent) exhibited signs of cerebral ischemia. After the clamp was opened, 5 of the patients were left with permanent neurological deficits, 15 died, and the rest recovered normally (no data were available on two patients). Other complications listed by Tindall include erosion of the artery, infection, hemorrhage from the neck wound, and nerve injury. Tindall believes that the procedure, although characterized by rather serious complications, is nonetheless an effective treatment for some types of aneurysms because of the far greater dangers of death or neurological injury presented by the untreated aneurysm and because of the difficulties involved in a direct surgical attack on the aneurysm.

Although most clamps are constructed of stainless steel, there is at least one report of brass (a biologically unacceptable material) being used as a component in a clamp (Ref. 3). However, no reports regarding the biological compatibility of carotid artery clamps have been found.

Although it is conceivable that, if not designed properly, the mechanism used to couple the adjusting stem to the clamp could injure the blood vessel, no reports of such injury have been found in the literature. Virtually all complications that have been reported are related to the risks associated with the carotid ligation procedure rather than to any particular device. The carotid artery clamp allows more gradual occlusion than does ligation by suture.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Tindall, G. T., "Management of Aneurysms of Anterior Circulation by Carotid Artery Occlusion," in *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Sunders Co., Philadelphia, PA, pp. 768-786, 1973.

2. Mount, Lester A., "Results of Treatment of Intracranial Aneurysms Using the Selverstone Clamp," *Journal of Neurosurgery*, 16:611-618, 1959.

3. Fuster, B., et al., "An Adjustable Clamp for use in Carotid Ligation," *Acta Neurologica Latinoamericana*, 16:224-230, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5175 as follows:

§ 882.5175 Carotid artery clamp.

(a) *Identification.* A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attack directly by reducing the blood pressure and blood flow to the aneurysm or malformation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32935 Filed 11-29-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1080]

MEDICAL DEVICES

Classification of Aneurysm Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aneurysm clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, on FDA advisory committee, made the following recommendation with respect to the classification of aneurysm clips:

1. Identification: An aneurysm clip is a device used to occlude an intracranial aneurysm (a ballonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the aneurysm clip be classified into class II (performance standards) because the performance of the clip needs to be reliable and the material used to construct the clip needs to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the aneurysm clip is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with aneurysm surgery and with this device. J. T. McFadden, M.D., a Panel member, has personal experience in the development of spring-loaded aneurysm clips, and has written about their problems and their successful application (Refs. 1, 2, and 3). A. U. Daniels, Ph. D., of the Utah Biomedical Test Laboratory (UBTL), presented to the Panel the results of a survey that showed that aneurysm clips are marketed in a great variety of designs, but that the manufacturers seldom specify the operating characteristics of the various types. John Tew, M.D., of the Mayfield Neurological Institute, presented to the Panel a review of aneurysm clip development and discussed the steps required to develop a standard. Dr. Tew, who is also chairman of the Working Group on Aneurysm and Blood Vessel Clips under the American Society for Testing and Materials (STM), discussed the progress ASTM is making toward developing a standard.

5. Risks to health: (a) Slippage of the clip may result in hemorrhage and possible death. If the clip does not maintain sufficient pressure, or if the jaw design does not provide sufficient friction, the clip may open or slide off the aneurysm after operation and allow the aneurysm to bleed. (b) cutting of the aneurysm or its parent vessel. In some designs, the "crotch" part of a clip may cut the arterial wall, or a clip having a sharp edge may accidentally cut the artery. (c) Tissue toxicity. Clips constructed of metals that are not biocompatible may cause an adverse tissue reaction.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that aneurysm clips be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation and has sought other data and documentation on aneurysm clips to determine if reasonable assurance of the safety and effectiveness of the device can be assured by performance standards. The Commissioner has found a considerable body of evidence to support the Panel recommendation. According to Fox, the first attempt to "clip" aneurysms probably occurred in 1911 and involved use of a soft metal device (Ref. 4). Spring clips, which were first employed in 1952 and have subsequently undergone improvements, have gained wide acceptance (Ref. 5 and 6). Since the late 1960's, the mortality rate for correction and intracranial aneurysms has decreased from approximately 25 percent to less than 5 percent due to several techniques that reduce the distance that the brain is moved during surgery (Ref. 7). Aneurysm clips have played a part in this improved mortality rate because they provide a means to repair large defects in an artery under the brain by access through a small opening (Ref. 3). Although failures of aneurysm clips are rare, they do occur (Ref. 8). Unsuccessful operations are more frequently related to incomplete occlusion of the aneurysmal sac because the clip slipped or was not applied properly (Ref. 9). Neurosurgeons have expressed a need for some means of comparing the characteristics of various clips (Ref. 10 and 11). A recent report describes a method and an instrument for testing aneurysm clips that may satisfy this need (Ref. 12).

Although the aneurysm clip is an implanted device that is of substantial importance in preventing impairment of human health, the Commissioner believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that general controls alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Chocked-Clip Aneurysmorrhaphy," *Surgery, Gynecology and Obstetrics*, 132:898, 1971.

2. McFadden, J. T., "Modifications of Crossed-Action Interacranial Clips," *Journal of Neurosurgery*, 32:116-118, 1970.

3. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1969.

4. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7:489-500, 1976.

5. Mayfield, F. H., and G. Kees, "A Brief History of the Development of the Mayfield Clip," *Journal of Neurosurgery*, 35:97-100, 1971.

6. Hiefetz, M. D., "A new Interacranial Aneurysm Clip," *Journal of Neurosurgery*, 30:763, 1969.

7. Fox, J. L., and G. R. Nugent, "Recent Advances in Intracranial Aneurysm Surgery, *West Virginia Medical Journal*, 72:104-106, 1976.

8. Servo, A., "Delayed Breaking of a Heifetz Aneurysm Clip," *Journal of Neurosurgery*, 47:463-465, 1977.

9. Drake, C. G., and J. M. Allcock, "Postoperative Angiography and the Slipped Clip," *Journal of Neurosurgery*, 39:683-689, 1973.

10. DeLong, W. B., "A Simple Method of Measuring Aneurysm Clip Tension," *Journal of Neurosurgery*, 47:788-789, 1977.

11. Sugita, K., et al, "Comparative Study of the Pressure of Various Aneurysm Clips," *Journal of Neurosurgery*, 44:723-727, 1976.

12. Aneurysm Clip Data Collection and *In Vitro* Testing, final Report TR 1603-003, Task Order No. 24 of Contract No. 223-74-5253, Utah Biomedical Test Laboratory, Salt Lake City, Utah 84108, May 10, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5200 as follows;

§ 882.5200 Aneurysm clip.

(a) *Identification.* An aneurysm clip is a device used to occlude an intracranial aneurysm (a ballonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32936 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1081]

MEDICAL DEVICES

Classification of Implanted Malleable Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted malleable clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of implanted malleable clips:

1. Identification: A implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude a blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that implanted malleable clips be classified into class II (performance standards) because the device Must be biologically compatible with tissue and must be structurally sound so that it will hold after application. The Panel recommends that a standard prohibit construction of implanted malleable clips from sterling silver because of the toxicity of this material. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the implanted malleable clip is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device. Implanted malleable clips have been used in neurosurgery since the early 1900's. Dr. J. T. McFadden, one of the Panel members, has published several journal articles on implantable metallic devices used in neurosurgery, such as the implanted malleable clip (Refs.*1, 2, 3, and 4). He has shown that clips made of sterling silver are especially reactive in tissue (Ref. 1).

5. Risks to health: (a) Local tissue reaction. An adverse tissue reaction may occur if the material used in the clip is not biocompatible. (b) Hemorrhage. Bleeding may occur if the clip is not structurally sound or fails to stay in place.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that implanted malleable clips be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation and has obtained additional data and information on implanted malleable clips to determine if reasonable assurance of the safety and effectiveness of the device can be assured by performance standards.

According to Fox, metal clips for use in neurosurgery were first described in 1911 (Ref. 5). Fox also described the different designs for malleable clips that have been used in neurosurgery. These clips were constructed of either sterling silver or tantalum. McFadden (Refs. 1, 2, and 3) states that tantalum produces the least tissue reaction, and Fox (Ref. 5) notes that the advantages of tantalum for malleable clip construction have been known since the 1940's. Although McFadden has shown that sterling silver produces the most tissue reaction of any of the metals commonly used in neurosurgery (Refs. 1, 2, and 3) clips made of sterling silver were very popular for many years and are still being marketed today.

The Commissioner believes that the establishment of performance standards for the implanted malleable clip is feasible considering the simplicity of the device and the existence of acceptable materials for its construction. However, the Commissioner requests comments on whether a performance standard established for implanted malleable clips should exclude the use of sterling silver as a material for constructing these devices, and whether, even before such a standard is established, FDA should consider regulatory action to remove sterling silver implanted malleable clips from the market.

Although the malleable clip is an implanted device, the Commissioner believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that general con-

trols alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:598-603, 1972.

2. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*," 31:373-385, 1969.

3. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

4. McFadden, J. T., "Chocked-clip Aneurysmorrhaphy," *Surgery, Gynecology and Obstetrics*, 132:898, 1971.

5. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7:489-499, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5225 as follows:

§ 882.5225 Implanted malleable clip.

(a) *Identification.* An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude a blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tisssue or a mechanical device in place in a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32937 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1082]

MEDICAL DEVICES

Classification of Aversive Conditioning Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aversive conditioning devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of aversive conditioning devices:

1. Identification: An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undersirable behavioral characteristics.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the aversive conditioning device be classified into class II (performance standards) because the device may apply an electrical current that may be hazardous to the patient. The Panel believes that general controls will not provide adequate control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendaton is based: The Panel members based their recommendation on their familiarity with these techniques. As summarized below, the risks to health presented by the device are well known.

Risks to health: (a) Worsened psychological condition. The patient's mental condition may become worse if aversive conditioning is administered incorrectly or if the patient is not carefully selected for this treatment. (b) Electrical shock. Leakage current from the device may injure the patient. (c) Patient injury. An aversive shock applied to the patient may be harmful or lethal if excessive current is used or if it is applied incorrectly.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that aversive conditioning devices be classified into class II (performance standards). Electrical shocking devices frequently have been used for aversive conditioning to treat various conditions (Refs. 1, 2, and 4). A loud bell that is electrically activated by the presence of moisture on a pad in the patient's bed has been used to treat enuresis (bedwetting) (Ref. 3). The Commissioner agrees with the Panel that these devices may apply an electrical current to the patient that may be hazardous. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Butterfield, W. H., "Electric Shock Hazards in Aversive Device Conditioning in Humans," *Behavioral Engineering*, 3:1-28, 1975

2. Logan, D. L. and J. R. Turnage, "Ethical Considerations in the Use of Faradic Aversion Therapy," *Behavioral Engineering*, 3:29-34, 1975

3. Thorne, D. E. "Instrumented Behavior Modification of Bedwetting," *Behavioral Engineering*, 2:47-52, 1975.

4. Johnson, J. B., "Electronic Aversive Conditioning," Proceedings of the 23rd Annual Conference on Engineering in Medicine and Biology, 1970, Washington, DC.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F, by adding new § 882.5235 as follows:

§ 882.5235 Aversive conditioning device.

(a) *Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undersirable behaviorial characteristics.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32938 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1083]

MEDICAL DEVICES

Classification of Burr Hole Covers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying burr hole covers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 201-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of burr hole covers:

1. Identification: A burr hole cover is a plastic or metal device used to cover or plug hole drilled into the skull during surgery and to reattach cranial bone removed during surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the burr hole cover be classified into class II (performance standards) because the material used in the device must be biocompatible and must be strong enough to protect the brain. The Panel believes that general controls will not provide sufficient control over these characteristics. The device is a simple plastic or metal plug. The Panel believes that, although the burr hole cover is an implant, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because sufficient information exists to develop a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the personal clinical experiences of the Panel members with these devices and their knowledge of the techniques, devices, and materials used in cranioplasty (repair of the skull).

5. Risks to health: (a) Local tissue reaction. The material used to construct the device may have a toxic effect if it is not biocompatible. (b) Structural failure. The material may fracture or break and expose the brain to injury if the material is not strong enough.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the burr hole cover be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify burr hole covers into class II (performance standards) and has obtained additional data and information to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by performance standards. There is a limited amount of published literature that deals directly with burr hole covers (Refs. 1 and 2). However, the materials used in burr hole covers (silicone, tantalum, and acrylic) also have been used extensively in other applications, e.g., cranial repair, and have been found to elicit minimal local tissue reaction (Refs. 3 and 4). Complications from use of burr hole covers are similar to those from use of other cranioplasty devices. Erosion of the skin over the implant due to friction pressure (Ref. 4), latent infection (Ref. 5), and discomfort or headache caused by the thermal conductivity of metallic implants (Ref. 4) have been reported in the literature as complications from use of various cranial implants and probably would occur also with the use of burr hole covers. The major hazard associated with burr hole covers, as with other implants, is the potential risk of excessive tissue reaction if a material is used that is not biocompatible; however, the literature suggests that this hazard is minimal because the materials used to construct burr hole covers have been reported to have satisfactory biocompatibility (Refs. 3, 4, and 6). FDA has found no reports in the literature of structural problems with burr hole covers.

The Commissioner agrees with the Panel that general controls will not provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also agrees that premarket approval is not necessary for this implanted device because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons,

from 9 a.m. to 4 p.m., Monday through Friday.

1. Todd, E. M. and B. L. Crue, "Burr-Hole Buttons for Fixation of Craniotomy Bone," *Journal of Neurosurgery*, 20:448-449, 1963.

2. Vallfors, B. and D. Forster, "An Alternative Method for the Fixation of Bone Flaps After Craniotomy, "Journal of Neurosurgery, 37:620, 1972.

3. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, CA, pp. 8-4 and 14-2 to 14-32, 1971.

4. Timmons, R. L., "Cranial Defects and Their Repair," *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

5. Mirabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-9, 1974.

6. McFadden, J. T., "Tissue reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 35:593-603, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5250 to read as follows:

§ 882.5250 Burr hole cover.

(a) *Identification.* A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32939 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1084]

MEDICAL DEVICES

Classification of Nerve Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nerve cuffs into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of nerve cuffs:

1. Identification: A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nerve cuff be classified into class III (premarket approval) because satisfactory performance has not been demonstrated for this implanted device and the Panel believes that there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The Panel has changed its recommendation concerning the classification of this device. At the Panel meeting of August 20-21, 1977, the Panel members recommended that the nerve cuff be classified into class II (performance standards) because the device is simple in design and uses a material (silicone) that is widely accepted as biocompatible. However, at the Panel meeting on April 21, 1978, the Panel reassessed its previous recommendation and recommended that the nerve cuff be classified instead into class III (premarket approval) because the device is an implant and there is serious doubt that the device is safe and effective when used to repair nerves. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal experience with nerve cuffs, and familiarity with the literature on this device. A recent report (Ref. 1) states that better results are obtained by stitching the nerve together without the use of the nerve cuff.

5. Risks to health: (a) Tissue reaction: The material that is used to construct the device may have a toxic effect if it is not biocompatible: (b) Infection: Infection may result if the device is not sterile. (c) Neuroma formation: The device may act as an irritant which may cause excess growth of neural tissue. (d) Foreign body contamination: Contaminants in the material of which the device is constructed may cause it to disintegrate and contaminate the nerve site.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the nerve cuff be classified into class III (premarket approval).

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of this device. The Commissioner believes that the published literature (Refs. 1, 2, and 3) supports the Panel's recommendation that the nerve cuff be classified into class III. In addition to the risks to health cited by the Panel, Szal and Milles report that swelling of the nerve after surgery may result in destruction of the repaired nerve if the diameter of the cuff is not sufficiently large (Ref. 1). Szal and Milles also report that the nerve cuff might, under some conditions, actually impede the healing of the nerve.

The Commissioner believes that this implanted device presents a potential unreasonable risk of illness or injury to the patient if it is ineffective. Furthermore, the device is for a use (aid in repairing nerves) which is of substantial importance in preventing impairment of human health. The Commissioner concurs that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effec-

tiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Szal, G. J. and T. Milles, "Surgical Repairs of Facial Nerve Branches," *Archives of Otolaryngology*, 101:160-165, 1975.

2. Midgley, R. D. and F. M. Woolhouse, "Silicone Rubber Sheathing as an Adjunct to Neural Anastomosis," *Surgical Clinics of North America*, 48:1149-1154, 1968.

3. Bucker, T. B. and George J. Haynes, "Experimental Improvements in the Use of Silastic Cuff for Peripheral Nerve Repair," *Journal of Neurosurgery*, 28:582-587, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5257 as follows:

§ 882.5275 **Nerve cuff.**

(a) *Identification.* A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the information of neuroma (tumors).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32940 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1085]

MEDICAL DEVICES

Classification of Methyl Methacrylate for Cranioplasty

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying methyl methacrylate for cranioplasty (skull repair) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of methyl methacrylate for cranioplasty:

1. Identification: Methyl methacrylate for cranioplasty (skull repair) is self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that methyl methacrylate for cranioplasty be classified into class II (performance standards) because scientific and medical data are available to establish the safety and effectiveness of methyl methacrylate for this use. Although methyl methacrylate for cranioplasty is implanted in the patient's skull, the Panel believes that premarket approval of this device is not necessary because methyl methacrylate has been used extensively for cranioplasty and has been shown to be safe and effective. The hazards associated with the use of methyl methacrylate can be avoided by controlling its chemical composition and by following preparation procedures. The panel believes that general controls will not provide sufficient control over these characteristics.

The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in cranioplasty. Methyl methacrylate has been used since the 1940's for repairing skull defects and is widely used today (Ref. 1). Some Panel members have served on the subcommittee under the American Society for Testing and materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Heat damage of tissue: The material generates heat as it polymerizes and hardens. If the material is not cooled, adjacent tissue can be injured by the heat. (b) Loss of brain protection: If the cranioplasty plate is made from material that is not sufficiently strong, it may be earily broken and allow brain injury. (c) Tissue toxicity: Impurities in some formulations may be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the methyl methacrylate for cranioplasty be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify methyl methacrylate for cranioplasty into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of this material.

The medical literature contains extensive reports on acrylic cranioplasty, including a thorough review by Timmons (Ref. 1) of the repair of cranial defects and the methods and materials that have been used for cranioplasty since the turn of the century. Timmons observes that the use of methyl methacrylate for repairing cranial defects has been common since the 1940's and has become very popular because its use avoids some of the problems of cranioplasty using metal plates. For example, acrylic is not ra-

diopaque and thus will not interfere with future x-ray diagnosis of the patient. In addition, acrylic cranioplasty plates also do not conduct heat very easily and, thus, avoid the problems of headache or patient discomfort that have been reported when metal cranioplasty plates are exposed to temperature extremes (Ref. 1). One of the advantages of acrylic is the ease with which it can be formed in place to fit precisely a skull defect.

Several reports in the medical literature show that there are, however, certain disadvantages and risks involved in using acrylic for cranioplasty. The polymerization reaction involved in forming the acrylic plate produces a great deal of heat that can damage the brain or other tissue (Refs. 1, 2, and 3). Fortunately, the surgeon can protect the brain from the heat with moist cottonoid strips, or can dissipate the heat by irrigating with a cold solution (Refs. 1 and 2). A technique was recently reported involving preparation of a plastic of paris model of the skull defect and formation and hardening of the acrylic plate to fit the model, without contact with the patient's skull (Ref. 3).

Another disadvantage of acrylic is that it is brittle and can be fractured by a relatively minor blow (Refs. 1, 4, and 6). To overcome this problem, acrylic has been reinforced using metal mesh made of stainless steel, aluminum, or tantalum (Refs. 1, 5, 6, and 7). Stainless steel and tantalum are radiopaque, however, and x-ray diagnosis may be hindered if these materials are used to reinforce acrylic.

There are also complications with acrylic cranioplasty that are common to all cranioplasty materials, including metals. Infection, erosion of the skin over the implant, and foreign body reaction to the implant have been reported (Refs. 1 and 2). Skin erosion over the implant may occur in regions where the scalp is thin if the plate has sharp or uneven edges. Some degree of foreign body reaction occurs with all implanted materials. However, methyl methacrylate acrylic is generally regarded as biologically safe for cranioplasty (Refs. 1, 2, and 8).

The Commissioner agrees with the Panel that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. The Commissioner also agrees with the Panel that a performance standard is necessary for this device because general controls would not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Timmons, R. L., "Cranial Defects and Their Repair," *in* "Neurological Surgery," Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

2. Hammon, W. M. and L. G. Kempe, "Methyl Methacrylate Cranioplasty: 13 Years Experience with 417 Patients," *Acta Neurochirurgica*, 25:69-77, 1971.

3. Asimacopoulos, T. J., et al., "A New Method of Cranioplasty," *Journal of Neurosurgery*, 47:790-92, 1977.

4. Henry, H. M., et al., "Cerebrospinal Fluid Fistula from Fractured Acrylic Cranioplasty Plate," *Journal of Neurosurgery*, 45:227-8, 1976.

5. Sessions, R. B., et al., "Wire Mesh Foundation for Methyl Methacrylate Cranioplasty," *Laryngoscope*, 84:1020-30, 1974.

6. Lake, P. A., et al., "Radiolucent Prosthesis of Mesh-Reinforced Acrylic," *Journal of Neurosurgery*, 27:376-78, 1967.

7. Galicich, J. H. and K. H. Hovind, "Stainless Steel Mesh-Acrylic Cranioplasty," *Journal of Neurosurgery*, 27:376-78, 1967.

8. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadenia, California, pp. 8-4 to 8-5 and 14-2 to 14-32, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5300 as follows:

§ 882.5300 Methyl methacrylate for cranioplasty.

(a) *Identification.* Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32941 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1086]

MEDICAL DEVICES

Classification of Preformed Alterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed alterable cranioplasty plates into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of preformed alterable cranioplasty plates:

1. Identification: A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that preformed alterable cranioplasty plates be classified into class II (performance standards) because the materials that are used in these plates must be biocompatible and strong. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes, however, that the materials that have been used for these plates have been proven acceptable through many years of use and that biological compatibility of these materials can be assured by establishment of standards for the composition of the materials. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in those plates. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Loss of brain protection: If the device is not sufficiently strong, it may bend or break and may cause brain injury. (b) Tissue toxicity: If the materials used to construct the device are not biocompatible, they may corrode and cause toxic reactions.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the preformed alterable cranioplasty plate be classified into class II (performace standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed alterable cranioplasty plates into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. The Commissioner has found that surgeons have used several metals and plastics for cranioplasty plates. However, the Commissioner believes that all commercially available preformed cranioplasty plates are constructed of vitallium, tantalum, or stainless steel. Although aluminum (Ref. 3), silicone (Ref. 4), polyethylene (Refs. 2, 5, and 6), titanium (Refs. 2 and 8), and zirconium (Ref. 2) have also been used by surgeons for cranioplasty plates, the Commissioner is unaware of any commercially available preformed cranioplasty plates made of these materials. The Commissioner requests comments on whether materials other than vitallium, tantalum, or stainless steel have been used in commercially available preformed cranioplasty plates.

Several reports in the medical literature discuss corrosion of metals used for cranioplasty plates. Most metals used for cranioplasty plates are protected form corrosion by a natural oxide coating that forms on the metal (Ref. 1). If the oxide coating is disturbed by cutting, drilling, hammering, or other manipulation during surgery, the plate may corrode excessively after implantation. Tantalum has an oxide coating that is tough enough to permit the plate to be reshaped without undergoing excessive corrosion. McFadden states that tantalum can be modified by cutting, bending, hammering, drilling, or other manipulation without changing the material's chemical behavior. McFadden states that stainless steel should never be altered when used as an implant (Ref. 1).

Timmons has thoroughly reviewed the repair of cranial defects and has described the methods and materials that have been used for cranioplasty since the turn of the century (Ref. 2). According to Timmons, the metal tantalum has been used extensively for cranioplasty because of its malleability, light weight, strength, and biological inertness. McFadden has reported that tantalum produced very little tissue reaction compared with other popular metals used in neurosurgery (Refs. 10 and 11). Tantalum is, however, a radiopaque material, and useful x-rays of the skull are difficult to obtain after implantation of a tantalum plate.

Complications common to virtually all cranioplasty plates, whether metal or plastic, are infection, erosion of the skin over the implant, and foreign body reaction to the implant (Ref. 2). Infection requiring removal of the plate has been reported as long as 17 years after implantation (Ref. 9). Skin erosion over the implant may occur in regions where the scalp is thin because the plate has sharp or uneven edges (Ref. 2). Some degree of foreign body reaction occurs with all implanted materials. If handled properly, however, the plastics and metals (with the possible exception of aluminum) that have been used for cranioplasty are generally regarded as biologically safe (Refs. 1 through 11).

Because of the high thermal conductivity of the metal, metal cranioplasty plates may cause headache or patient discomfort when the plates are exposed to temperature extremes (Ref. 2). In addition, a metal plate may be deformed by a blow to the head, although this occurrence is rare (Ref. 5). Another possible drawback of metal implants is that they leave a dead space between the implant and the brain; there has been debate whether this dead space might result in brain herniation (abnormal protrusion) (Ref. 2).

Plastic or acrylic cranioplasty does not share some of the problems presented by metal cranioplasty. Plastics do not corrode and may be cut or modified to fit the particular patient. Because plastic and acrylic implants do not conduct heat as readily as metals, they do not cause temperature-induced headaches. Plastics are, however, weaker than metals and need to be made thicker to achieve sufficient strength. Acrylic plates are brittle and easily cracked (Ref. 2). Polyethylene and silicone implants, however, are flexible and are less likely to be deformed by blows than are metal plates.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, form 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. Timmons, R. L., "Cranial Defects and Their Repair," *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

3. Black, S. P. W., et al., "Aluminum Cranioplasty," *Journal of Neurosurgery*, 29:562-564, 1968.

4. Courtemanche, A. D. and G. B. Thompson, "Silastic Cranioplasty Following Cranio-Facial Injuries," *Pastic and Reconstructive Surgery*, 41:165-170, 1968.

5. Karvounis, D. C., et al., "The Use of Prefabricated Polyethylene Plate for Cranioplasty," *Journal of Trauma*, 10:149-154, 1970.

6. Polisar, R. S. and A. W. Cook, "Use of Polyethylene in Cranial Implants," *Journal of Prosthetic Dentistry*, 29:310-316, 1973.

7. Simpson, D., "Titanium in Cranioplasty," *Journal of Neurosurgery*, 22:292-293, 1965.

8. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Chapter 14, Pasadena Technology Press, Pasadena, CA, 1971.

9. Merabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-399, 1974.

10. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:595-603, 1972.
11. McFadden, J. T., "Metallurgical Principles in Neurosurgery," Journal of Neurosurgery, 31:373-385, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5320 as follows:

882.5320 Preformed alterable cranioplasty plate.

(a) *Identification.* A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32942 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1087]

MEDICAL DEVICES

Classification of Preformed Nonalterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed nonalterable cranioplasty plates into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of preformed nonalterable cranioplasty plates:

1. Identification: A preformed nonalterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that preformed nonalterable cranioplasty plates be classified into class II (performance standards) because the materials that are used in these plates must be biocompatible and strong. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes, however, that the materials that have been used for these plates have been proven acceptable through many years of use and that biological compatibility of these materials can be assured by establishment of standards for the composition of the materials. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in those plates. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Loss of brain protection: If the device is not sufficiently strong, it may bend or break and may cause brain injury. (b) Tissue toxicity: If the materials used to construct the device are not biocompatible, they may corrode and cause toxic reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the preformed nonalterable cranioplasty plate be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed nonalterable cranioplasty plates into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. The Commissioner has found that several metals and plastics have been used by surgeons over the years for cranioplasty plates. However, the Commissioner believes that all commercially available preformed cranioplasty plates are constructed of vitallium, tantalum, or stainless steel. The Commissioner requests comments on whether materials other than vitallium, tantalum, or stainless steel have been used in commercially available preformed cranioplasty plates.

Several reports in the medical literature discuss corrosion of metals used for cranioplasty plates. Most metals used for cranioplasty plates are protected from corrosion by a natural oxide coating that forms on the metal (Ref. 1). If the oxide coating is disturbed by cutting, drilling, hammering, or other manipulation during surgery, the plate may corrode excessively after implantation. Some metals, e.g., tantalum, have oxide coatings that are tough enough to permit reshaping of the plate without causing excessive corrosion.

Several types of stainless steel have been used in constructing various implantable devices. Scott used Type 316 stainless steel for cranioplasty plates and reports it to be the most corrosion resistant of the stainless steels (Ref. 2). McFadden states, however, that stainless steel should never be altered by cutting, bending, drilling, or other manipulation at the time of surgery because of the tendency of stainless steel to corrode faster if its external oxide coating is disturbed (Ref. 1).

Vitallium is a very hard alloy of cobalt, chromium, and molybdenum that has been used in orthopedic implantable devices, but has received very little attention in neurosurgery because it is not malleable and is difficult to work with. McFadden (Ref. 1) rates the corrosion resistance of vitallium as better than stainless steel and worse than tantalum. Vitallium cannot be altered, and its use in neurosurgery has been confined to preformed nonalterable cranioplasty plates and the screws for such plates (Refs. 1, 2, and 4).

Complications common to virtually all cranioplasty plates are infection, erosion of the skin over the implant, and foreign body reaction to the implant (Ref. 2). Infection requiring removal of the plate has been reported as long as 17 years after implantation (Ref. 5). Skin erosion over the implant may occur in regions where the scalp is thin because the plate has sharp or uneven edges (Ref. 2). Some degree of foreign body reaction occurs with all implanted materials. If handled properly, stainless steel and vitallium are, however, generally regarded as biologically safe (Refs. 1 through 4). Because of the high thermal conductivity of the metal, metal cranioplasty plates may cause headache or patient discomfort when the plates are exposed to temperature extremes (Ref. 2). In addition, a metal plate may be deformed by a blow to the head, although this occurrence is rare. Another possible drawback of metal implants is that they leave a dead space between the implant and the brain; there has been debate whether this dead space might result in brain herniation (abnormal protrusion) (Ref. 2).

Plastic or acrylic cranioplasty does not share some of the problems presented by metal cranioplasty. Plastics do not corrode and may be cut or modified to fit the particular patient. Because plastic and acrylic implants do not conduct heat as readily as metals, they do not cause temperature-induced headaches. Plastics are, however, weaker than metals and need to be made thicker to achieve sufficient strength. Acrylic plates are brittle and easily cracked (Ref. 2). However, polyethylene and silicone implants are flexible and are less likely to be deformed by blows than are metal plates.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. Timmons, R. L., "Cranial Defects and Their Repair," "Neurological Surgery," Vol. 2, edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

3. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:595-603, 1972.

4. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1968.

5. Merabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-399, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5330 as follows:

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32943 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1088]

MEDICAL DEVICES

Classification of Cranioplasty Plate Fasteners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranioplasty plate fasteners into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cranioplasty plate fasteners:

1. Identification: A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cranioplasty plate fasteners be classified into class

II (performance standards) because a standard governing the composition of materials that are used in the fasteners should require that the materials be both biocompatible and compatible with the material used in the cranioplasty plate. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their personal clinical experience with cranioplasty plates and the devices used to fasten those plates to the skull. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Tissue toxicity: If the material used to construct the cranioplasty plate fastener is not biocompatible or is not compatible with the material used in the cranioplasty plate, it may corrode and cause a toxic reaction. (b) Loss of structural integrity: If the material used to construct the cranioplasty plate fastener is not compatible with the material used in the cranioplasty plate, corrosion of the fastener and plate may weaken the plate, causing the brain to be exposed to possible injury.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cranioplasty plate fastener be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify cranioplasty plate fasteners into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Tantalum, vitallium, and stainless steel in the form of screws, metal wedges, and wire have been used to fasten cranioplasty plates to the skull. McFadden stresses that the chemical behavior of stainless steel wire will change if it is twisted or tied, and corrosion will ultimately occur (Refs. 1 and 2). He suggests that tantalum wire be used if the wire is to be buried in tissue. Dispite wide use of the cranioplasty plate fastener in cranioplasty, FDA has found no cases of complications directly associated with the cranioplasty plate fastener. It is, however, generally acknowledged that the fastener should be constructed of the same material as the cranioplasty plate to avoid galvanic corrosion (Refs. 1 and 2). The materials used for cranioplasty plate fasteners are generally regarded as biocompatible if handled properly (Refs. 1 through 4).

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1968.

3. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:598-603, 1972.

4. Timmons, R. L., "Cranial Defects and Their Repair," *in* "Neurological Surgery," Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5360 as follows:

§ 882.5360 **Cranioplasty plate fastener.**

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32944 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1089]

MEDICAL DEVICES

Classification of Lesion Temperature Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lesion temperature monitors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of lesion temperature monitors:

1. Identification: A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesson generator and probe.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the lesion temperature monitor be classified into class II (performance standards) because the surgeon uses the device with a radiofrequency lesion generator to destroy selectively, for therapeutic purposes, very small parts of a patient's brain, spinal cord, or other tissue. The Panel believes that the device needs to measure the temperature accurately and reliably because the surgeon relies on the lesion temperature monitor to detect the temperature of the tissue at the lesion site so that the surgeon can control the amount of destruction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.

5. Risks to health: Inappropriate sized lesions. A temperature indication that is inaccurate or imprecise may lead the surgeon to form lesions that are too small or too large. Forming a lesion that is too small may not have the desired therapeutic benefit, and forming a lesion that is too large may destroy normal tissue and cause an undesired neurological deficit in the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the lesion temperature monitors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5500 as follows:

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesion generator and probe.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32945 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1090]

MEDICAL DEVICES

Classification of Central Nervous System fluid Shunts and Components

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying central nervous system fluid shunts and components into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification central nervous system fluid shunts and components:

1. Identification: A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that central nervous system fluid shunts and their components be classified into class II (performance standards) because there is sufficient information available to establish performance standards that will assure the safety and effectiveness of these devices. Shunts have been used for many years to treat hydrocephalus. Hydrocephalus is a condition, usually in children, characterized by an accumulation of cerebrospinal fluid (CSF) in the head. The CSF causes the head to enlarge and may produce brain damage by fluid pressure. The Panel believes that the characteristics of central nervous system fluid shunts and their components are reasonably well established and that the conditions being treated are reasonably well understood. Although the Panel believes that the materials that have been used in the device are generally regarded as safe, it recommends establishment of standards to assure consistency in the composition of the materials. In addition, the panel believes it is important for the physician to know the pressure-flow characteristics of the valves used in shunts, to compare available valves, and to select the correct valve for a particular patient. Accordingly, the Panel recommends that the manufacturers of shunt valves be required to state, in standard form, the pressure-flow characteristics of their valves and to use standard test procedures to obtain measurements of those characteristics. The panel believes that general controls will not provide sufficient control over the above characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of devices in this category, which includes internal, totally implanted shunts; external temporary devices that drain CSF to an external receptacle; and components of both internal and external shunts. The Panel recommends that internal and external shunts and their components be classified in a single classification regulation because the shunts share the same characteristics that should be addressed in performance standards and because the components are used with a shunt

as a system. The Panel notes that a standard is being developed by the American Society for Testing and Materials (ASTM) and recommends that this standard, when completed, be adopted by the FDA.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the relevant literature on these devices and on testimony and advice from Dr. Larry page, a Panel consultant. There has been extensive literature published on these devices in the 27 years of their clinical use. The published literature shows that although use of shunts is associated with death rates and mental retardation rates that may seem high, these rates are much lower than those for patients with untreated hydrocephalus. The death rate for patients with untreated hydrocephalus is 40 to 70 percent, compared with a death rate of 5 to 35 percent for patients treated with ventriculoatrial shunts (Ref. 1). The mental retardation rate among survivors with untreated hydrocephalus is 50 to 85 percent compared with a mental retardation rate of 20 to 50 percent among treated survivors (Ref. 1). The complications associated with these devices have been extensively reported in the literature and are well known to the Panel members.

5. Risks to health: (a) Abnormal intracranial pressure: Mechanical malfunctioning of the shunt or its components (e.g., blockage of the catheter or valve) may result in elevated intracranial pressure and the return of symptoms of hydrocephalus. (b) Tissue toxicity: Adverse tissue reactions may result if the shunt or component materials are not biocapatible. (c) Perforation of viscus: The tip of the catheter may puncture the bladder or other organs if the catheter material is too stiff. (d) Infection: Infection may result if the shunt or its components are not sterile or introduce contaminants into the patient.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the central nervous system fluid shunts and their components be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify central nervous system fluid shunts and their components into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of these devices. Shunting devices have been used for several decades to treat hydrocephalus and other conditions that result in an increased intracranial pressure because of an abnormal accumulation of fluid in the bentricles (cavities) of the brain. If untreated, this condition usually results in death or sever mental retardation of the patient.

Several methods of shunting have been used to relieve the pressure of excess cerebrospinal fluid (CSF). All methods consist of a catheter that diverts the CSF, either to an external bag (external shunt) or to the blood stream or another part of the body (internal shunt). An external shunt uses a catheter that drains the CSF from the ventricles of the brain into a colleciton bag outside the body and is used only for short-term applications. Internal shunts are, however, totally implanted catheters intended to be used for long-term (chronic) relief of hydrocephalus. The most popular methods of internal shunting are the ventriculoatrial shunt, which diverts CSF from the ventricles of the brain to the right atrium of the heart, where the CSF is released into the blood stream; and the ventriculoperitoneal shunt, which diverts CSF from the ventricles of the brain to the peritoneal cavity, where it is reabsorbed by the body. Internal shunts have also been used, though less frequently, to divert CSF from the subarachnoid space of the spine to the peritoneal cavity (lumboperitoneal shunt) and from the ventricles of the brain to the pleural cavity (ventriculopleural shunt), the ureter (ventriculoureteral shunt), and the thoracic lymph duct (ventriculolymphatic shunt).

A study by Milhorat, described above in the panel recommendation, shows that shunting has significantly reduced the mortality and mental retardation resulting from hydrocephalus (Ref. 1). Numerous other reports have similarly verified that various forms of shunting are effective in relieving the often disastrous effects of elevated CSF pressure.

The obvious and undeniable benefits of this treatment have, however, been accompanied by a large number of complications. The complications vary depending upon the shunting technique and the anatomical site to which the CSF is delivered. Complications common to most shunting techniques include obstruction or malfunction of the shunt, infection, and tissue reaction, e.g., formation of a fibrous sheath around the catheter or erosion of tissue over the shunt (Refs. 1, 5, and 7). Ventriculoatrial shunts have been associated with unique cardiopulmonary complications because of the placement of one end of the catheter in the blood stream. Among these complications are pulmonary emboli, caused by clotting at the catheter tip or by breakage or separation and release of the catheter into the blood stream (Refs. 1, 2, and 3), and perforation of the heart wall by the catheter tip (Refs. 1 and 3). In addition, glomerulonephritis (inflammation of the kidneys) has also been reported in patients with ventriculoatrial shunts (Ref. 4). Ventriculoperitoneal shunts also have been associated with unique complications, such as perforation of the bladder or other organs by the catheter tip (Refs. 8, 9, and 10), and development of inguinal (groin) hernias (Ref. 8), intra-abdominal cysts (Refs. 6 and 8), and ascites (CSF collection in the abdominal cavity) (Ref. 6). Lumboperitoneal shunts have been associated with scoliosis (deviation in the straightness of the spine), leg pain or atrophy, and restricted back movement (Refs. 11 and 12). There have been few reports on complications associated with ventriculopleural, ventriculoureteral, and ventriculolymphatic shunts because these methods are so rarely used. However, Milhorat believes that removal of a kidney, which must precede use of a ventriculoureteral shunt, is a procedure that presents undue risk (Ref. 1).

The Commissioner believes that premarket approval is unnecessary for these devices because there is sufficient information to establish a performance standard that will provide reasonable assurance of their safety and effectiveness. Although there are many complications associated with shunts, the Commissioner recognizes that shunts are generally used when no alternatives exist and that they have reduced the death and mental retardation rates associated with hydrocephalus. Moreover, the Commissioner doubts that requirement premarket approval of these devices will improve the complication rate associated with their use.

The Neurological Device Classification Panel recommended that all central nervous system fluid shunts, both internal and external, and their components be classified into class II (performance standards). although FDA is proposing to adopt this recommendation, the agency requests comments on whether it would instead classify each shunt component (e.g., catheters, valves, connectors, collection bags, etc.) separately from the classification of shunts. The Commissioner believes that it is possible that some of these components (e.g., collection bags for external shunts) could be classified more appropriately into class I.

The Commissioner also requests comments on whether the agency should classify shunts according to the technique used (internal or external) and the anatomical site to which the CSF is delivered, instead of classifying all shunts as a single product, as proposed. The Commissioner recognizes that, depending on the type of shunt used, there may be substantial differences in the number and severity of complications. In addition, there is much more information available on the more common shunt techniques (e.g., ventriculoatrial shunts) than is available on other less frequently used shunts (e.g. ventriculolymphatic shunts).

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

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4. McKenzie, S.A. and K. Hyden, "Two Cases of 'Shunt Nephritis'," *Pediatrics*, 54:806-808, 1974.

5. Becker, D. P. and F. E. Nulsen, "Control of Hydrocephalus by Valve-Regulated Venous Shunt: Avoidance of Complications in Prolonged Shunt Maintenance, "*Journal of Neurosurgery*, 28:215-226, 1968.

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7. Sugar, O. and O.T. Bailey, "Subcutaneous Reaction to Silicone in Ventriculoperitoneal Shunts," *Journal of Neurosurgery*, 41:367-371, 1974.

8. Grosfield, J. L., et al., "Intraabdominal Complications Following Ventriculoperitoneal Shunt Procedures," *Pediatrics*, 54:791-796, 1974.

9. Robertson, J.S., et al., "Ventriculoperitoneal Shunting for Hydrocephalus," *British Medical Journal*, 2:289-292, 1973.

10. Hoffman, H.S., et al., "New Lumboperitoneal Shunt for Communicating Hydrocephalus," *Journal of Neurosurgery*, 44: 258-261, 1976.

11. Eisenberg, H. M., et al., "Lumboperitoneal Shunts: A Review of 34 Cases," *Journal of Neurosurgery*, 35:427-431, 1971.

12. Kushner, J., et al., "Kyphoscoliosis Following Lumbar Subarachnoid Shunts," *Journal of Neurosurgery*, 34:783-791, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5550 as follows:

§ 882.550 Central nervous system fluid shunt and components.

(a) *Identification.* A central nervous system fluid shunt is a device or combination of devices use to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial presssure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catherters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc.78 32946 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1091]

MEDICAL DEVICES

Classification of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranial electrotherapy stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cranial electrotherapy stimulators:

1. Identification: A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

2. Recommended classification: Class II (premarket approval). The Panel recommends that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cranial electrotherapy stimulators be classified into class III (premarket approval) because satisfactory effectiveness has not been demonstrated. In addition, the Panel believes that it is not possible to establish an adequate performance standard for this device because the characteristics of the electrical current necessary for effectiveness are not known. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that the device present a potential unreasonable risk of illness or injury to the patient if the practitioner relies on the device, and it is ineffective in treating the patient's illness. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

At the Panel meeting of July 22-23, 1977, the Panel recommended that this device be classified into class II (performance standards) if it is used to treat situational anxiety related to alcohol and drug addiction and class III (premarket approval) if it is used to treat insomnia, depression, or other conditions. At that meeting, the Panel members stated that, although the published literature does not support the effectiveness of this device for any conditions, the evidence that the device is effective in treating situational anxiety related to alcohol or drug addiction is stronger than the evidence concerning treatment of other conditions for which the device has been prescribed. At a Panel meeting on January 13, 1978, however, the Panel reassessed its recommendation on cranial electrotherapy stimulators and recommended that the device be classified into class III (premarket approval) for all uses, including treatment of situational anxiety related to alcohol or drug addiction

because the Panel members believe that there has been no clear demonstration of the effectiveness of this device for treating any conditions.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on testimony presented to the Panel and on the results of a study performed by the National Research Council (NRC) on the safety and effectiveness of devices used for electroanesthesia and electrosleep (Ref. 1). Drs. Ray Smith and Timothy Sharma presented the results of their studies of cranial electrotherapy stimulation for detoxification of drug and alcohol addicts. These researchers stated that they believe this treatment to be more effective than other standard approaches used to treat alcohol or drug addiction. They maintained that there have been virtually no reports of hazards or injuries associated with the treatment. However, after reviewing the results of 88 published studies on cranial electrotherapy stimulation, the NRC concluded that the device has not been shown to be effective in treating any of the conditions for which it is prescribed (Ref. 1). The NRC report found, however, that the output current of the device is sufficiently low that there is little hazard to the patient from the current.

5. Risks to health: (a) Skin irritation: The electrodes or the conductive cream used with the electrodes may cause skin irritation. (b) Worsening of the condition being treated: If the device is not effective and the patient is not treated in a conventional manner, the patient's psychological condition may worsen.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cranial electrotherapy stimulator be classified into class III (premarket appoval). The Commissioner believes that this device is for a use (treatment of insomnia, depression, or anxiety) which is of substantial importance in preventing impairment of human health. Furthermore, the device presents a potential unreasonable risk of illness or injury to the patient if the practitioner uses it instead of conventional therapy to treat severe psychological conditions. He concurs that insufficient information exists to determine that general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

"An Evaluation of Electroanesthesia and Electrosleep," National Research Council, FDA Contract 70-22, Task Order No. 20 (NTIS PB 241305).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5800 as follows:

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32947 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1092]

MEDICAL DEVICES

Classification of External Functional Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing for public comment a proposed regulation classifying external functional neuromuscular stimulators into class II (performance standards). The FDA is also publishing the recommendations of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Administrative Proceedings Staff/Hearing Clerk's Office (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committee, made the following recommendation with respect to the classification of external functional neuromuscular stimulators:

1. Identification: An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

2. Recommended classification: Class II (performance standards). The Neurological Device Classification Panel recommends that establishing performance standards for this device be a low priority. The Physical Medicine Device Classification Panel recommends that establishing performance standards for this device be a high priority.

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel and the Neurological Device Classification Panel recommend that external functional neuromuscular stimulators be classified into class II (performance standards) because the device applies an electrical current to the patient's body and both Panels believe that this current should be controlled to prevent injuring the patient. Both Panels also believe that the performance characteristics of the device must be controlled to assure that the device is safe and effective for its use. The Physical Medicine Device Classification Panel also recommends that the device not be used on patients with cardiac pacemakers and that caution be exercised when it is used on patients with anesthetized limbs. Both the Physical Medicine Device Classification Panel and the Neurological Device Classifi-

cation Panel believe that general controls will not provide sufficient control over the above characteristics. Both Panels also believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to provide such assurance.

4. Summary of data on which the recommendation is based: The members of the Physical Medicine Device Classification Panel and the Neurological Device Classification Panel based their recommendation on their clinical experience with this device and with other external stimulators similar to this device.

5. Risks to health: The Physical Medicine Device Classification Panel identified the following risks to health: (a) Skin reactions: The conductive gel used for the electrodes may cause skin reactions. (b) Skin burns: The patient's skin may be burned if the output current level is excessive or if the electrodes are too small. (c) Ineffectiveness of treatment: If the current level of the stimulator is not sufficient or if the electrodes are not the proper size, the stimulation may be ineffective.

The Neurological Device Classification Panel identified the following risks to health: (a) Skin burns: The patient's skin may be burned if the output current is excessive or if the electrodes are too small. (b) Skin reactions: The patient's skin may be irritated at the electrode site because of the presence of the electrodes and the conductive gel.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendation of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel and is proposing that the external functional neuromuscular stimulator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5810 as follows:

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification.* An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Administrative Proceedings Staff/Hearing Clerk's Office (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32948 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1093]

MEDICAL DEVICES

Classification of Implanted Cerebellar Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted cerebellar stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted cerebellar stimulators:

1. Identification: An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device that involves a substantial risk to the patient and there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on extensive testimony and data received by the Panel from investigators and clinicians who have used the device. Because there is much disagreement among investigators as to the safety and effectiveness of the device, the Panel initially had difficulty deciding whether the device should be recommended for classification into class II or class III. The results of experimental studies on animals to determine brain damage or other adverse effects caused by electrically stimulating the cerebellar cortex were reported to the Panel. Some investigators reported finding minimal or no brain damage caused by the stimulating current, while others reported distinct changes and damage to the cerebella of test animals. Investigators also reported results of studies concerning the effectiveness of the device in reducing the frequency of epileptic seizures and the degree of spasticity in patients. The investigators reported widely varying degrees of success in treating those disorders. The Panel concluded that insufficient information exists to establish a performance stand-

ard that would assure the safety and effectiveness of this device. A summary of the testimony and data presented to the Panel by each investigator is contained in the minutes of the Panel meetings of April 8-9, 1976 and July 22-23, 1977. The minutes of those meetings may be obtained from the Hearing Clerk, Food and Drug Administration, at the address given elsewhere in this document.

5. Risks to health: (a) Injury to neural tissue. The electrical current used for stimulation and the pressure that the electrodes exert on the brain tissue may cause injury to the brain. (b) Cerebrospinal fluid leakage: The fluid that surrounds the brain may leak out where the electrode wires pass through the skull. (c) Tissue toxicity: The surface material of the implanted device, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that implanted cerebellar stimulators be classified into class III (premarket approval). The Commissioner believes that the implanted cerebellar stimulator presents a potential unreasonable risk of illness or injury to the patient because of the possibility of neural damage. Furthermore, the device is for uses (reducing the severity and frequency of epileptic seizures, or reducing spasticity due to cerebral palsy) which are of substantial importance in preventing impairment of human health. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5820 as follows:

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification.* An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32949 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1094]

MEDICAL DEVICES

Classification of Implanted Diaphragmatic/Phrenic Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted diaphragmatic/phrenic nerve stimulators into class III (premarket approval). The FDA is also publishing the recommendations of two FDA advisory committees concerning these devices. The Neurological Device Classification Panel and the Anesthesiology Device Classification Panel both recommend that implanted diaphragmatic/phrenic nerve stimulators be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after its publication in the FEDERAL REGISTER.

ADDRESS: Written comments (preferably four copies) to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Anesthesiology Device Classification Panel, FDA Advisory Committees, made the following recommendations with respect to the classification of implanted diaphragmatic/phrenic nerve stimulators:

1. Identification: An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hyperventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that this device be classified into class III (premarket approval). Both Panels recommend that premarket approval for this device be a high priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III (premarket approval) because the device is a life supporting implant that has been used by only a limited number of clinical investigators and is not a well-established medical procedure. Although the reported clinical results have been favorable, this device presents a serious risk of injuring the patient's phrenic nerve and thus causing permanent injury. At the Panel meeting of August 20-21, 1977, the Neurological Device Classification Panel recommended that this device be classified into class II (performance standards because the Panel believed that the device has been shown to be safe and effective. However, at the meeting of the Neurological Device Classification Panel on April 21, 1978, the Panel reassessed its previous recommendation on this device and recommended that it be classified into class III (premarket approval) instead because the clinical results available were limited to one company's device. The Panel did not believe that the results were sufficient to establish a performance standard for the device. The Panels do not believe that there is sufficient information to establish a performance standard that will provide reasonable assur-

ance of the safety and effectiveness of the device. The Panels also believe that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Neurological Device Classification Panel members based their recommendation on their clinical experience with this device and their knowledge of the medical literature published on the device. The Anesthesiology Device Classification Panel members based their recommendation on a lack of medical data on which to judge the safety and effectiveness of the device.

5. Risks to health: The Neurological Device Classification Panel identified the following risks to health from this device. (a) Respiratory arrest: If the device fails or if the stimulation becomes ineffective, the patient may stop breathing. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible. (c) Injury to phrenic nerve: The patient's phrenic nerve may be injured by excessive electrical current, improper electrodes, or surgical trauma. The Anesthesiology Device Classification Panel identified the following risks to health: (a) Hypoventilation: The patient may not be able to breathe sufficiently if the device fails. (b) Hyperventilation: The patient may be forced by the device to breathe too rapidly if the rate control on the device fails.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel and is proposing that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III (premarket approval). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, because trauma to the patient's phrenic nerve due to placement of the electrode around the nerve may cause permanent injury that impairs breathing. Furthermore, the device is an implant that is for a life-supporting use (producing or aiding breathing). The act requries the Commissioner to classify an implant or a life-supporting device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. Although the reported clinical results with this device have been favorable (Ref. 1), the Commissioner concurs with the Panels that insufficient information exists on this implanted life-supporting device to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that would provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

Glenn, W. W. L., "Diaphragm Pacing: Present Status," *Pace* 1:357-370, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5830 as follows:

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification.* An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerves to contract the diaphragm rhythmically and produce breathing in patients who have hyperventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32950 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1095]

MEDICAL DEVICES

Classification of Implanted Intracerebral/Subcortical Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted intracerebral/subcortical stimulators for pain relief into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted intracerebral/subcortical stimulator for pain relief:

1. Identification: An implanted intracerebral/subcortical stimulators for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator con-

sists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device. In addition, although the Panel considered recommending that the device be classified into class II, it concluded that there is not sufficient information available to establish that the device is safe and effective for treating pain. Although some investigators report that they have had success with this technique, the Panel members express doubt that the results could be replicated by others. The electrodes of this device must penetrate the brain, and the Panel believes that this surgery involves a substantial risk to the patient. Although the reported clinical results with these devices have been favorable, the Panel believes that sufficient information is not available to establish a performance standard for the device that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device and similar devices. In addition, the Panel members are familiar with the literature published on this device (Refs. 1, 2, and 3).

5. Risks to health: (a) Injury to neural tissue: The electrical current used for stimulation may damage the brain. (b) Hemorrhage or physical disruption of neural tissue: The insertion of the device electrodes may sever blood vessels and destroy brain tissue. (c) Tissue toxicity: The materials used in the implanted portion of this device may be toxic to brain or other tissues. (d) Cerebrospinal fluid leakage: The fluid which surrounds the brain may leak out around the connecting wires of the device that penetrate the skull.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the implanted intracerebral/subcortical stimulator for pain relief be classified into class III (premarket approval). The Commissioner believes that this implanted device presents a potential unreasonable risk of illness or injury to the patient because of the possibility of neural damage. Furthermore, the device is for a use (treatment of severe intractable pain) which is of substantial importance in preventing impairment of human health. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Pudenz, R. H., "Adverse Effects of Electrical Energy Applied to the Nervous System," *Neurosurgery* 1:190-191, 1977.

2. Adams, J. E. and Y. Hosobuchi, "Session on Deep Brain Stimulation: Technique and Technical Problems," *Neurosurgery* 1:196-199, 1977.

3. Richardson, D. E. and H. Akil, "Long Term Results of Periventricular Gray Self-Stimulation," *Neurosurgery* 1:199-202, 1977.

Therefore, under the Federal Food, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5840 as follows:

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief

(a) *Identification.* An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32951 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1096]

MEDICAL DEVICES

Classification of Implanted Spinal Cord Stimulators for Bladder Evacuation

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted spinal cord stimulators for bladder evacuation into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted spinal cord stimulators for bladder evacuation:

1. Identification: An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is

unable to emplty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device, and there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. At the Panel meeting of August 20-21, 1977, the Panel recommended that this device be classified into class II (performance standards) because the device is similar in design to the implanted spinal cord stimulator for pain relief which the Panel recommended to be classified into class II. However, on April 21, 1978 the Panel reassessed its recommendation on implanted spinal cord stimulators for bladder evacuation and recommended that they be classified into class III (premarket approval) because the device has been successfully applied in only a small number of patients, and virtually all those patients were treated by one physician using a device manufactured by one company. Although the reported clinical results with those patients has been favorable, the Panel believes that there is not enough information to establish a performance standard for the device that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on information supplied by Dr. Blaine Nashold, one of the Panel members, who has been one of the primary individuals engaged in the development of the device. Dr. Nashold reported that he has implanted the device in a small group of paraplegic patients. Six of the 12 patients have been successfully emptying their bladders by this method for the past 5 years (Ref. 1).

Risks to health: (a) Injury to neural tissue: Tissue fibrosis may develop around the electrode on the spinal cord and cause a diminished response to the electrical stimulus. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material which is not biocompatible. (c) Cerebrospinal fluid leakage: The fluid that surrounds the spinal cord might leak out around the receiver wires.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that implanted spinal cord stimulators for bladder evacuation be classified into class III (premarket approval). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury, because of the possibility of neural damage. Furthermore, the Commissioner believes that this implanted device is for a use (bladder evacuation in paraplegic patients) which is of substantial importance in preventing impairment of human health. The act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nashold, B. S., et al., "Operative Stimulation of the Neurogenic Bladder," Proceedings of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:218-220, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 is Subpart F by adding New § 882.5850 as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

(a) *Identification.* An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32952 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1097]

MEDICAL DEVICES

Classification of Implanted Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted neuromuscular stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III and the recommendation of the Orthopedic Device Classification Panel that the device be classified into class II. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Orthopedic Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of implanted neuromuscular stimulators:

1. Identification: An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel of the patient's shoe.

2. Recommended classification: The Orthopedic Device Classification Panel recommends that this device be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Neurological Device Classification Panel recommends that this device be classified into class III (premarket approval) and that premarket approval for the device be a high priority.

3. Summary of reasons for recommendation: The Orthopedic Device Classification Panel recommends that this device be classified into class II (performance standards) because the device uses materials that are implanted and should be controlled. This Panel believes that use of this device is contraindicated in patients with cardiac pacemakers because of the possibility that the stimulator may interfere with the operation of the pacemaker. The Orthopedic Device Classification Panel further recommends that the device be restricted to sale by or on the order of a physician. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

The Neurological Device Classification Panel recommends that the implanted neuromuscular stimulator be classified into class III (premarket approval) because the device is a surgical implant that has been used on only a limited number of patients. At the Panel meeting of August 20-21, 1977, the Neurological Device Classification Panel recommended that the device be classified into class II (performance standards) because the Panel at that time believed the device had been shown to be safe and effective. However, at the meeting of the Neurological Device Classification Panel on April 21, 1978, the Panel reassessed its previous recommendation on this device and recommended that it be classified into class III (premarket approval) instead because the clinical results available were limited to one company's device which had been used on only a few patients. The Neurological Device Classification Panel does not believe that there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also believes that there is not sufficient information available on this device to show that general controls alone are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal knowledge of the device, the potential hazards associated with the device, the pertinent literature (Ref. 1), and their clinical experience with the device.

5. Risks to health: The Orthopedic Device Classification Panel identified the following risks to health: (a) Adverse tissue response: The materials used in the device may cause a toxic or adverse reaction in the surrounding tissue. (b) Infection: There is an increased risk of sepsis associated with the presence of a foreign object implanted in the body.

The Neurological Device Classification Panel identified the following risks to health: (a) Injury to the nerve: The presence of the electrode or the output current may injure the peroneal or femoral nerve. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendation of the Neurological Device Classification Panel and is proposing that the implanted neuromuscular stimulator be classified into class III (premarket approval). The Commissioner does not agree with the Orthopedic Device Classification Panel that sufficient information is available on this device to establish a performance standard that will assure the safety and effectiveness of the device. The Commissioner notes that there are only limited clinical data available on this device, and most of the data are from one medical center using a device manufactured by one company. A recent publication states that only 31 patients have had the device implanted to improve their walking (Ref. 2). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, because of the possibility of nerual damage. Furthermore, the device is an implant for a use (improving the gait in a patient with a paralyzed leg) which is of substantial importance in preventing impairment of human health. The act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. Therefore, the commissioner concurs with the Neurological Device Classification Panel that insufficient information exists on this implanted device to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and the Commissioner believes that insufficient information exists to establish a performance standard that would provide such assurance.

The following information has been placed in the office of the hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

REFERENCES

1. National Academy of Sciences, "Clinical Evaluation of Rancho Los Amigos/Medtronic Implanted Neuromuscular Assist Device," Committee on Prosthetic Research and Development, In Press, 1976.

2. McNeal, D. R., et al., "Experience with Implanted Electrodes," Proceedings of the symposium on the Safety and clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:228-229, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him 21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5860 as follows:

§ 882.5860 Implanted neuromuscular stimulator.

(a) *Identification.* An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals

may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32953 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1098]

MEDICAL DEVICES

Classification of Implanted Peripheral Nerve Stimulators For Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted peripheral nerve stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, on FDA advisory committee, made the following recommendation with respect to the classification of implanted peripheral nerve stimulators for pain relief:

1. Identification: An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class II (performance standards). The Panel recommends that performance standards for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because the performance of the device should be controlled to avoid injury to the nerve that is stimulated and because the implanted materials used in the device should be required to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with these devices and their familiarity with the relevant literature.

5. Risks to health: (a) Injury to neural tissue: The nerve that is stimulated may be damaged by the presence of the electrode or by the output current from the device. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implanted peripheral nerve stimulator for pain relief be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify implanted peripheral nerve stimulators for pain relief into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Electrical stimulation of peripheral nerves has been used to relieve chronic intractable pain, produced primarily by trauma or injury to nerves. The device consists of electrodes that are placed around a peripheral nerve in a patient and connected by lead wires to a receiver that is placed in a convenient spot just under the skin. The stimulating pulses are transmitted acress the skin to the receiver by an external radiofrequency transmitter and an antenna that is placed on the skin over the receiver.

The major benefit of using this device is that patients with chronic intractable pain may be able to reduce their pain to such an extent that they can reduce or eliminate the use of analgesic drugs. Several authors have reported that peripheral nerve stimulation provides significant relief to patients with chronic intractable pain. This technique has been reported to be effective in about 55 percent of the patients on whom it was attempted (Refs. 1, 2, 3, and 4). The most common nerves that are stimulated are the sciatic, ulnar, occipital, and femoral nerves. There have been few reports of complications involving this technique. Picaza (Ref. 1) reports that the most common complication in 37 patients followed for 12 to 46 months was tenderness at the receiver implantation site or at the electrode site. He also reports two cases of formation of neuroma (a small tumor on the nerve) at the electrode site. Picaza cautions, however, that implanted stimulators should be used only in those cases where continued stimulation is necessary for long periods of time, because patients often can obtain satisfactory relief by using external transcutaneous stimulation.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary of this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Picaza, J. A., et al., "Pain Suppression: Chronic Effects," Proceedings of the symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:226-227, 1977.

2. Nashold, B. S. and J. L. Goldner, "Electrical Stimulation of Peripheral nerves for Relief of Intractable Chronic Pain," *Medical Instrumentation*, 9:224-225, 1975.

3. Erickson, D. and S. Chou, "Implantable Electrical Devices for pain Relief," *Minnesota Medicine*, 57:210-212, 1974.

4. Long, D. M., "Electrical Stimulation for Relief of Pain from Chronic Nerve Injury," *Journal of Neurosurgery*, 39:718-722, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546

(21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5870 as follows:

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) *Identification.* An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32954 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1099]

MEDICAL DEVICES

Classification of Implanted Spinal Cord Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted spinal cord stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-30), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted spinal cord stimulators for pain relief:

1. Identification: An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because the performance of the device should be controlled to avoid injuring the patient's spinal cord and because the implanted materials used in the device should be required to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device and their knowledge of the relevant literature.

5. Risks to health: (a) Injury to neural tissue: The patient's spinal cord may be damaged by the presence of the electrodes or by the output current from the device. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible. (c) Cerebrospinal fluid leakage: The fluid which surrounds the spinal cord (cerebrospinal fluid) may leak out around the electrode lead wires.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implanted spinal cord stimulator for pain relief be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify implanted spinal cord stimulators for pain relief into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Electrical stimulation of the spinal cord for relief of pain has been used by numerous clinicians since the technique was introduced in the 1960's. The stimulation apparatus consists of electrodes that are placed at the desired location on the patient's spinal cord and connected by wires to a receiver that is located in a convenient spot just under the skin. The stimulating pulses are transmitted across the skin to the receiver by an external radiofrequency transmitter and an antenna that is placed on the skin over the receiver. The major benefit of using this device is that patients with chronic intractable pain may be able to reduce their pain to such an extent that they are able to reduce or eliminate the use of analgesic drugs.

The placement of the device's electrodes on the spinal cord has been an important factor in the complication rates for this device. Electrodes are usually placed on the dorsal (back) side of the spinal cord either within the dura (the outer membrane surrounding the spinal cord), below the dura, or below the arachnoid membrane of the spinal cord (Ref. 1). These methods require major surgery to implant the electrodes. Recently, a technique has been used where the electrodes are inserted through a needle into the epidural (outside or on the dura) space, thus greatly reducing the necessary surgery (Refs. 1, 2, and 3).

The reported long-term, good-to-excellent results obtained with implanted spinal cord stimulators for treating pain has varied from about 17 percent (Ref. 4) to over 80 percent (Refs. 3 and 5). Generally, however, the device has been reported to be effective in about 40 to 60 percent of the patients treated (Refs. 1, 2, 6, 7, and 8). Nashold observed that effectiveness of the device in his group tended to decrease with time, while the level of stimulation required for effectiveness tended to in-

crease with time (Ref. 7). Virtually all authors agree, however, that the key to successful application of the device is careful selection of the patients on whom it is used.

Complications or problems with spinal cord stimulation have been reported by several investigators. Fox lists 26 problems or comments that were reported to him in his survey of 10 neurosurgeons who used these devices (Ref. 1). Others have also reported a variety of problems. The complications reported include spinal cord compression or injury by the electrode, resulting in transient paralysis (Refs. 1, 2, 6, 8, and 9); leakage of cerebrospinal fluid around the lead wires (Refs. 1, 7, and 8); thickening of the arachn membrane of the spinal cord (Refs. 1 and 7); rejection of the implant or tissue reaction (Refs. 2 and 8); and infection (Ref. 1). Grillo, et al. reported one case where the patient was temporarily paralyzed when bleeding occurred beneath a subarachnoid electrode 18 months after it was implanted (Ref. 9).

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

REFERENCES

1. Fox, J. L., "Problems Encountered with Implanted Electrodes for Dorsal Column Stimulation for Pain," *in* "Functional Electrical Stimulation," Edited by F. T. Hambrecht and J. R. Reswick, Marcel Dekker, Inc., New York, pp. 459-463, 1977.

2. Burton, C. V., "Safety and Clinical Efficacy," Proceedings of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive devices, *Neurosurgery*, 1:214-215.

3. North, R. B., et al., "Chronic Stimulation via Percutaneously Inserted Epidural Electrodes," Proceeding of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery, 1:215—218.*

4. Long, D. M. and D. E. Erickson, "Stimulation of the Posterior Columns of the Spinal Cord for relief of Intractable Pain," *Surgical Neurology*, 4:134-141, 1975.

5. Nielson, K. D., et al., "Phantom Limb Pain: Treatment with Dorsal Column Stimulation," *Journal of Neurosurgery*, 42:301-307, 1975.

6. Nashold, B. S. and H. Friedman, "Dorsal Column Stimulation for Control of Pain: Preliminary Report on 30 Patients," *Journal of Neurosurgery*, 36:590-597, 1972.

7. Nashold, B. S., "Dorsal Column Stimulation for Control of Pain: A Three-Year Follow-up," *Surgical Neurology*, 4:146-147, 1975.

8. Sweet, W. H. and J. G. Wepsic, "Stimulation of the Posterior Columns of the Spinal Cord for Pain Control: Indications, Technique and Results," *Clinical Neurosurgery*, 21:278-310, 1974.

9. Grillo, P. J., et al., "Delayed Intraspinal Hemorrhage after Dorsal Column Stimulation For Pain," *Archives of Neurology*, 30:105-106, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5880 as follows:

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) *Identification.* An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Interested persons may on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32955 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1100]

MEDICAL DEVICES

Classification of Transcutaneous Electrical Nerve Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transcutaneous electrical nerve stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of transcutaneous electrical nerve stimulators for pain relief:

1. Identification: A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that transcutaneous electrical nerve stimulators for pain relief be classified into class II (performance standards) because the patient may be injured if the device is used incorrectly or if the output current is excessive. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive personal clinical experience with this device, data presented by experts in the use of the device, and a review of the relevant literature on the device. A summary of the literature reviewed was prepared by the Panel (Ref. 1). Users of transcutaneous electrical nerve stimulator devices have reported that long-term (1 year or more) effectiveness of this device in treating pain is about 25 to 30 percent for selected patients who have intractable chronic pain. The best results were obtained on patients who had chronic low back pain, phantom limb pain, and pain of osteoarthritis. The literature contains no reports of mortalities caused by this device.

5. Risks to health: (a) Burns. The patient's skin may be burned if the output current levels are excessive or if the electrodes are too small. (b) Skin reactions. The conductive cream or gel used with the electrodes or the presence of the electrodes on the skin may cause adverse skin reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the transcutaneous electrical nerve stimulator for pain relief be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Report on the Findings and Recommendations on Transcutaneous Electrical Nerve Stimulation for Pain Relief," prepared by the Panel on Review of Neurological Devices, Food and Drug Administration, February 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5890 as follows:

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32956 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1101]

MEDICAL DEVICES

Classification of Preformed Craniosynostosis Strips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed craniosynostosis strips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of preformed craniosynostosis strips:

1. Identification: A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to assure that the material used in craniosynostosis strips is biocompatible and performs properly. The Panel believes that general controls will not provide sufficient control over these characteristics. Although preformed craniosynostosis strips are implanted devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information availabe to establish a standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and the literature related to biocompatibility.

5. Risks to health: (a) Risk of ineffective treatment: If the material does not maintain its structural integrity, it will fail to prevent the bone from growing back together. (b) Tissue toxicity: The material used in the device may cause adverse tissue reaction if it is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that preformed craniosynostosis strips be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed craniosynostosis strips into class II (performance standard) and has obtained additional data and information on the safety and effectiveness of the device. Shillito provides a detailed explanation of the procedure and reports improvement in 74 percent of 519 infants (Ref. 1) He reported two deaths and an overall complication

rate of 14 percent in that group. The more serious complications included wound sepsis, hematoma, tears in the dura, erosion through the scalp of the clips holding the plastic strip in place, septicemia, and permanent scarring of the forehead caused by the pressure of the surgical head rest. Polyethylene film and silicone rubber strips have been used in the treatment of craniosynostosis and are generally regarded as biologically compatible (Ref. 2).

The Commissioner agrees with the Panel that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. The Commissioner also agrees with the Panel that a performance standard is necessary for this device because general controls would not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Shillito, J., Jr., "Craniosynostosis," *in* "Neurological Surgery," Vol. 1, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 608-627, 1973.

2. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, Calif., pp. 14-2 to 14-32.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5900 as follows:

§ 882.5900 Preformed craniosynostosis strips.

(a) *Identification.* A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32957 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1102]

MEDICAL DEVICES

Classification of Dura Substitutes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dura substitutes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological and Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of dura substitutes:

1. Identification: A dura substitute is a sheet of material that is used to repair the dura mater (the membrane surrounding the brain).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II performance standards) because the material should be required to be biocompatible and to be able to maintain a seal to prevent cerebrospinal fluid (CSF) leakage. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Tissue reaction: The material used in the device may be toxic to surrounding tissue, or may adhere to neural tissue. (b) CSF leakage: If the material does not maintain a seal with the dura, or if defects in the material occur, the CSF may leak out.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the dura substitute be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of this implanted device. Since the turn of the century, a wide variety of both natural and synthetic materials has been used to seal holes in the dura mater (Ref. 1). The natural materials have included both processed and unprocessed tissues. Numerous synthetic materials have been used. According to several authors, dura substitutes must have three basic qualities: biocompatibility; the ability to prevent tissue adhesions between the cerebral cortex and overlying soft tissue; and the ability to prevent cerebrospinal fluid (CSF) leakage (Refs. 1 through 3). CSF leakage has been reported to be a problem, especially with woven materials (Ref. 4). Tantalum foil has the disadvantages of being radiopaque and of being easily torn (Ref. 4). Silicone film dura replacement has been reported to have been associated with two cases of intracranial bleeding (Ref. 4). Infection also is an inherent risk with any operative procedure involving an implant such as the dura substitute.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to es-

tablish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Keener, E. B., "Regeneration of Dural Defects," *Journal of Neurosurgery*, 16:415-423, 1957.

2. Lee, J. F., et al., "Experimental Evaluation of Silicone Coated Dacron and Collagen Fabric Film Laminate as Dural Substitute," *Journal of Neurosurgery*, 27:558-564, 1967.

3. Abin, S. M., et al., "Nonsuture Sealing of a Dural Substitute Utilizing a Plastic Adhesive Methyl 2-Cyanoacrylate," *Journal of Neurosurgery*, 19:545-550, 1962.

4. Banerjee, T., et al., "Unusual Complications with Use of Silastic Dural Substitute," *American Surgeon*, 40:434-437, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5910 as follows:

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet of material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32958 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1103]

MEDICAL DEVICES

Classification of Electroconvulsive Therapy Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroconvulsive therapy devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroconvulsive therapy devices:

1. Identification: An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances, e.g., severe depression, by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electroconvulsive therapy (ECT) devices be classified into class II (performance standards) because the devices must be capable of providing the correct amount of current to the patient to induce a seizure without unnecessarily injuring the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the use of this device involves a substantial risk to the patient, the Panel believes that the benefit of the treatment outweighs the risks involved if the patients are selected carefully and the devices are designed and used properly. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal familiarity with the use of this device and on information provided by Dr. Allen R. Grahn of the Utah Biomedical Test Laboratory. Dr. Grahn conducted a study under contract to the FDA on ECT devices and presented the results of his study to the panel (Ref. 1). Dr. Grahn's study was based on a review of the scientific literature, information supplied by ECT device manufacturers, and a survey of ECT users. He pointed out that the optimum electrical characteristics of ECT devices have not been determined but that a reliable therapeutic result may be achieved using a variety of device electrical designs. Dr. Grahn also stated that no controlled study has been performed that determines precisely the mortality associated with ECT treatments. However, estimates predict a mortality frequency that ranges from one death per 10,000 treatments to one death per 28,000 treatments (Ref. 1).

5. Risks to health: (a) Burns: Excessive electrical current or improperly designed electrodes may cause the patient's skin under the electrodes to be burned. (b) Pain: The patient is subjected to pain if the device fails to administer sufficient current to achieve a convulsive seizure. (c) Brain damage: Excessive or improper control of the applied electrical current may produce injury to the patient's brain. (d) Self-injury during seizure: Inadequate supportive drug treatment may allow the patient to be injured from unconscious violent movements during convulsions. (e) Aspiration: The patient may inhale foreign material, such as regurgitated stomach contents, if preventive procedures are not employed. (f) Adverse drug effects: The muscle relaxing and tranquilizing drugs that are a part of the procedure may hamper the patient's ability to breathe spontaneously. (g) Cardiac arrhythmia: The therapeutic convulsions may be accompanied by irregular heartbeat or cardiac arrest. (h) Memory loss: The patient may suffer amnesia after the treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electroconvulsive therapy devices be classified into class II (performance standards). The Commissioner believes that a performance

standard is necessary for this device because general controls by themselves are insufficient to control the risks to health described above. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

Grahn, Allen R., "Summary of Presentation to FDA Neurology Panel—Study of Electroconvulsive Therapy Device Safety and Efficacy," (Contract 223-74-5753, Task 22), October 15, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c. 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 is Subpart F by adding new § 882.5940 as follows:

§ 882.5940 Electroconvulsive therapy devices.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32959 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1104]

MEDICAL DEVICES

Classification of Artificial Embolization Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying artificial embolization devices into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of artificial embolization devices:

1. Identification: Artificial embolization devices are objects that are placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

2. Recommendd classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that artificial embolization devices be classified into class III (premarket approval) because the devices are permanent implants and the patient may be seriously injured if the physician is not able to ensure that the devices go to the selected target site after release into the blood stream. The Panel believes that there is not sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device, nor is there enough information to show that general controls will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the belief that there is insufficient clinical information which shows that artificial embolization devices are safe and effective for treating vascular malformations.

5. Risks to health: (a) Infarction of nervous tissue: The embolism can lodge in an unintended site after release into the blood stream. The embolism may then prevent blood from reaching healthy tissue and cause permanent damage to the nervous system. (b) Tissue toxicity: The material used in the device may produce a toxic reaction if it is not compatible with tissue or blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the artificial embolization device be classified into class III (premarket approval). The Commissioner believes that the device presents a potential risk of death or serious injury to the patient if the physician is unable to control the emboli or thrombus-forming material. Furthermore, the device is for a use (treatment of vascular malformations) which is of substantial importance in preventing impairment of human health. Finally, the device is an implant, which the act requires to be classified into class III unless the Commissioner determines that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary.

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of artificial embolization devices. Artificial embolization has been used to treat various patient conditions involving malformations of blood vessels or tumors in the brain or spinal cord. The most frequent method reported has been the use of radiopaque silicone spheres that are directed to the site where embolization is desired and released into the blood stream by means of a special catheter (Refs. 1 through 5). Various sizes and quantities of spheres are used depending on the size of the blood vessel to be

blocked. Investigators have also used gelfoam (Ref. 1), polyurethane foam (Ref. 6), liquid silicone (Ref. 1), and small bits of muscle (Ref. 7) to serve as artificial emboli. Alksne has developed and used a technique for treating intracranial aneurysms where iron particles are injected into the aneurysm and held in place by a magnetic field until the blood clots and closes the aneurysm (Refs. 8 through 10).

The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hilal, S. K., and J. W. Michelsen, "Therapeutic Percutaneous Embolization for Extra-Axial Vascular Lesions of the Head, Neck, and Spine," *Journal of Neurosurgery*, 43:275-287, 1975.

2. Luessenhop, A. J., and J. H. Presper, "Surgical Embolization of Cerebral Arteriovenous Malformations Through Internal Carotid and Vertebral Arteries," *Journal of Neurosurgery*, 42:443-451, 1975.

3. Pugatch, R. D., and S. M. Wolpert, "Transfemoral Embolization of an External Carotid-Cavernous Fistula," *Journal of Neurosurgery*, 42:94-97, 1975.

4. Kricheff, I. I., et al., "Transfemoral Catheter Embolization of Cerebral and Posterior Fossa Arteriovenous Malformations," *Neuroradiology*, 103:107-111. 1972.

5. Boulos, R., et al., "Value of Cerebral Angiography in the Embolization Treatment of Cerebral Arteriovenous Malformations," *Radiology*, 97:65-70, 1970.

6. Ohta, T., et al., "Closure of Carotid-Cavernous Fistula with Polyethylene Foam Embolus," *Journal of Neurosurgery*, 38:107-112, 1973.

7. Black, R., et al., "Carotid-Cavernous Fistula: A Controlled Embolus Technique for Occlusion of Fistula with Preservation of Carotid Blood Flow," *Journal of Neurosurgery*, 38:113-118, 1973.

8. Alksne, J. F., and R. W. Smith, "Iron-Acrylic Compound for Stereotaxic Aneurysm Thrombosis," *Journal of Neurosurgery*, 47:137-141, 1977.

9. Alksne, J. F., "Stereotactic Thrombosis of Intracranial Aneurysms," *New England Journal of Medicine*, 284:171-174, 1971.

10. Alksne, J. F., "Current Status of Metallic Thrombosis of Intracranial Aneurysms," *Progress in Neurological Surgery*, 3:212-229, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5950 as follows:

§ 882.5950 Artificial embolization device.

(a) *Identification.* Artificial embolization devices are objects that are placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32960 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1105]

MEDICAL DEVICES

Classification of Skull Tongs for Traction

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull tongs for traction into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull tongs for traction:

1. Identification: Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that skull tongs for traction be classified into class II (performance standards) because the pressure that the tong tips exert on the skull may injure the patient if the tong tips are not designed properly. The Panel believes that the design of these devices is particularly important because of the possible serious consequences to the patient should the device slip out or penetrate the skull. The Panel believes that general controls will not provide sufficient control of these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device. Skull tongs for traction have been used clinically for several decades.

5. Risks to health: (a) Infection: Because the tips of the skull tongs penetrate the skin and must be left in place for a long period of time, infection is an inherent risk. (b) Necrosis: The pressure of the tong tips may kill skull or scalp tissue. (c) Neurological injury or death: If the device collapses or pulls out of the skull a significant injury to the spinal cord or death may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that skull tongs for traction be classified into class II (performance standards). The Commissioner believes that a performance standard is neces-

sary for this device because general controls by themselves are not sufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5960 as follows:

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32961 Filed 11-27-78; 8:45 am]